IN THE UNITED STATES DISTRICT COURT
FOR THE DISTRICT OF MASSACHUSETTS
BOSTON DIVISION

UNITED STATES OF AMERICA *ex rel.* James Banigan and Richard Templin	§	
STATE OF CALIFORNIA, *ex rel.* James Banigan and Richard Templin;	§	
STATE OF DELAWARE, *ex rel.* James Banigan and Richard Templin;	§	
DISTRICT OF COLUMBIA *ex rel.* James Banigan and Richard Templin;	§	
STATE OF FLORIDA *ex rel.* James Banigan and Richard Templin;	§	CIVIL NO. 07-12153-RWZ
STATE OF GEORGIA *ex rel.* James Banigan and Richard Templin;	§	
STATE OF HAWAII *ex rel.* James Banigan and Richard Templin;	§	
STATE OF ILLINOIS *ex rel.* James Banigan and Richard Templin;	§	
STATE OF INDIANA *ex rel.* James Banigan and Richard Templin;	§	**FILED IN CAMERA AND UNDER SEAL**
STATE OF LOUISIANA *ex rel.* James Banigan and Richard Templin;	§	
COMMONWEALTH OF MASSACHUSETTS *ex rel.* James Banigan and Richard Templin;	§	SECOND AMENDED COMPLAINT OF RELATORS JAMES BANIGAN AND RICHARD TEMPLIN PURSUANT TO FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS - Leave to File Granted on 3/11/10
STATE OF MICHIGAN *ex rel.* James Banigan and Richard Templin;	§	
STATE OF MONTANA *ex rel.* James Banigan and Richard Templin;	§	
STATE OF NEVADA *ex rel.* James Banigan and Richard Templin;	§	
STATE OF NEW HAMPSHIRE *ex rel.* James Banigan and Richard Templin;	§	
STATE OF NEW MEXICO *ex rel.* James Banigan and Richard Templin;	§	JURY TRIAL DEMANDED
STATE OF NEW YORK *ex rel.* James Banigan and Richard Templin;	§	
STATE OF OKLAHOMA *ex rel.* James Banigan and Richard Templin;	§	
STATE OF TENNESSEE *ex rel.* James Banigan and Richard Templin;	§	

STATE OF TEXAS *ex rel.*	§
James Banigan and Richard Templin;	§
COMMONWEALTH OF VIRGINIA *ex rel.*	§
James Banigan and Richard Templin;	§
STATE OF NEW JERSEY *ex rel.*	§
James Banigan and Richard Templin;	§
STATE OF RHODE ISLAND *ex rel.*	§
James Banigan and Richard Templin;	§
STATE OF WISCONSIN *ex rel.*	§
James Banigan and Richard Templin;	§
STATE OF CONNECTICUT *ex rel.*	§
James Banigan and Richard Templin;	§
STATE OF NORTH CAROLINA *ex rel.*	§
James Banigan and Richard Templin;	§
CITY OF CHICAGO *ex rel.*	§
James Banigan and Richard Templin;	§
	§
	§
Plaintiffs,	§
	§
	§
VS.	§
	§
	§
ORGANON USA INC.; OMNICARE, INC.;	§
PHARMERICA, INC.; ORGANON	§
BIOSCIENCES N.V.; SCHERING PLOUGH	§
CORP; AKZO NOBEL N.V.; ORGANON	§
INTERNATIONAL, INC; ORGANON	§
PHARMACEUTICALS USA, INC.; and	§
MERCK CO. & INC.	§
Defendants.	§

SECOND AMENDED COMPLAINT OF RELATORS JAMES BANIGAN AND RICHARD TEMPLIN PURSUANT TO FEDERAL FALSE CLAIMS ACT AND VARIOUS STATE FALSE CLAIMS ACTS

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1. The United States of America, the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago, by and through *qui tam* relators James Banigan and Richard Templin, bring this action under 31 U.S.C. §§ 3729–3732 (the "False Claims Act") to recover all damages, penalties and other remedies established by the False Claims Act on behalf of the United States and themselves and would show the following:

I. INTRODUCTION

2. This suit concerns pharmaceutical company Organon's seven-year scheme to offer unlawful enticements to long-term care pharmacies in exchange for prescribing its anti-depressants, Remeron Tablet and Remeron SolTab (collectively referred to as "Remeron"), to their patients, resulting in hundreds of millions of dollars in wrongful Medicaid prescription reimbursement costs.

3. In the late 1990's, following an explosion of new for-profit businesses delivering long-term care, and as those facilities and the pharmacies that served them began to consolidate into a handful of large, powerful companies, Organon began to focus its Remeron marketing efforts on the Medicaid-dominated long-term care sector. Beginning in 1999, Organon began offering special discounts exclusively to long-term care pharmacy providers, including "market tier" discounts that grew as the customer attained ever higher market share for Remeron compared with competitor drugs. These market share discounts constituted kickbacks – inducements designed to drive long-term care pharmacies'

promotion of Remeron over other antidepressants in a competitive field regardless of Remeron's clinical advantages or disadvantages.

4. Meanwhile, Organon was looking for a solution to a related threat. Following Remeron Tablet's patent expiration in 1998, Organon anticipated that generic competition, set to begin in 2001, could cause the company a catastrophic loss of profits. In the face of that threat, Organon sought approval from the Food and Drug Administration (the "FDA") for a variant form of Remeron—an orally disintegrating tablet called Remeron SolTab—that was not initially rated AB equivalent to Remeron Tablet, effectively barring generic competition for the variant form. By the time that Remeron SolTab was approved in January of 2001, Organon had concocted a new initiative to convert as many long-term care patients as possible from Remeron Tablets to the patent-protected Remeron SolTab, and to continue to win long-term care market share from competitors.

5. In late 2000, Organon began negotiating full-blown "therapeutic interchange" programs with its LTCPP customers, including nationwide chains PharMerica, Omnicare, NeighborCare, NCS Healthcare, APS, and Sunscript, under which these customers would convert Remeron Tablet prescriptions to patent-protected Remeron SolTab prescriptions, and would substitute other antidepressants for Remeron SolTab. Various tools to affect therapeutic interchange are within LTCPP customers' arsenals, and Organon sought to become a beneficiary of these tools, from educational initiatives, to mass mailings requesting authorization to change prescriptions, to "NDC locks" to block pharmacists' computers from dispensing disfavored drugs. In order to induce LTCPPs to adopt such therapeutic interchange programs, Organon offered a new array of kickbacks. Organon began to offer its market share inducements in the form of rebates rather than

discounts, in order to protect the inducements from disclosure in states in which Medicaid had begun to request actual invoices with pharmacist's reimbursement claims. It also added ramp-up discounts, "conversion" rebates tied to conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, and "therapeutic interchange" bonuses conditioned on LTCPPs bestowing Remeron Tablet and Remeron SolTab with a "preferred" status and engaging in an active therapeutic interchange program.

6. Organon's willingness to extend indefinitely its contractual ramp-up discounts containing the highest levels of discounts demonstrates that the rebates served solely as kickbacks. This ramp-up discount period was originally offered in February of 1999 and was intended to run only through June 1999; through various amendments, however, this ramp-up period was extended for years for many customers until it ultimately expired in the last remaining contracts on December 31, 2005 with the advent of Medicare Part D.

7. Organon funneled payments of various sorts to LTCPPs as additional incentive to accomplish therapeutic interchange. These collateral kickbacks, often solicited by the LTCPPS themselves, took the form of data sharing agreements for the purchase of LTCPP prescribing data, research grants, educational grants, access fees, sponsorship of long-term care pharmacy providers' annual meetings, advisory panels, and other forms of remuneration. Indeed, certain LTCPPs such as Omnicare solicited even more money in kickbacks than Organon could afford, and reserved their highest levels of participation for those willing and able to pay astronomical costs.

8. Organon's senior care sales team, at the instruction of high-level executives, also offered LTCPPs an "opportunity to profit" from Medicaid as added

incentive to prescribe Remeron over competitors. As the sales team described in detail to customers using profit calculators and models, visual aids, and the "Therapeutic Interchange Toolkit," Remeron SolTab boasted a greater "spread" between the pharmacies' costs for the drug and Medicaid reimbursement; a spread created by Organon's deep discounts and rebates on Remeron coupled with an inflated AWP.

9. Even in a retail pharmacy setting, in which Organon offered few price discounts or rebates because of the pharmacies' lesser influence on drug choice, and where the focus was solely on converting Remeron Tablet scripts to SolTab, Organon widely marketed the promise of better Medicaid reimbursement by virtue of SolTab's greater proportional "markup" between AWP and WAC. Organon sweetened the inducement to several retail chains by offering kickbacks in exchange for specific actions undertaken to affect the conversion.

10. Organon's sales pitch to long-term care was focused largely on financial advantages. But Organon also specifically trained long-term care pharmacists and their attending clinicians to maximize conversion of residents' anti-depressant prescriptions to Remeron by promoting Remeron's short-term side effects of somnolence and weight gain as though they were FDA-approved indications. In essence, Organon illegally held out the off-label promise of a more docile, easily controlled resident population in order to provide the clinical ruse to affect therapeutic interchange in the long-term care sector.

11. Organon made similar off-label claims in marketing Remeron outside of the long- term care sector as well as additional off-label claims seeking pediatric and other usage. In deliberately and deceptively marketing uses that had not been approved by the Food and Drug Administration ("FDA"), Organon caused Medicaid states to pay for

prescriptions that were tainted by illegal off-label promotion, and accompanied by illegal kickbacks to physicians in the form of gifts and other remuneration.

12. Organon's appeal to long-term care pharmacy providers to convert patients to Remeron Tablet and Remeron SolTab was spectacularly successful. In fact, the market shares attained in long-term care were three times greater than any other market sector, fueled by Medicaid's dominance as a payor in long-term care. Remeron was Organon's top selling drug from 1999 to 2005. Remeron sales from 1999 to 2004 totaled an estimated $693 million in Medicaid sales, with $347.5 million in long-term care sales.

13. Further, by engaging in this scheme to defraud Medicaid and other federal healthcare programs with long-term pharmacy providers, such as PharMerica and Omnicare, as well as group purchasing organizations, Organon effectively reduced its liability for Remeron Tablet and Remeron SolTab under its rebate agreement with Medicaid. When calculating its average manufacturer price, Organon included as a deduction the deep discounts offered on Remeron Tablet and Remeron SolTab to long-term care customers, even though the discounts constituted illegal kickbacks, thus decreasing its average manufacturer price, which lowered its rebate liability to Medicaid accordingly. In addition, Organon hid its true "best price" from the Government by entering into separate agreements with long-term care pharmacy providers that essentially amounted to kickbacks. By failing to disclose to Medicaid that these payments that it provided to long-term pharmacy providers, Organon concealed its true "best price" to Medicaid, thereby lowering its rebate liability to Medicaid.

14. Organon also falsely reported pricing for a number of transactions involving Remeron Tablet and Remeron SolTab, further lowering the rebate it paid to state

Medicaid programs. For example, Organon on two occasions sold a high volume of Remeron SolTab to Omnicare and PharMerica at "bargain basement" prices in exchange for the simultaneous purchase of more Remeron SolTab at normal commercial prices without reporting these transactions together to Medicaid, thereby lowering the Organon's rebate liability to state Medicaid programs. Similarly, in 2001, realizing that discounts on Remeron provided under a 1997 fixed-price contract with Kaiser Permanente ("Kaiser") were setting a best price, Organon sought to amend this contract to increase the price of Remeron in exchange for providing the same amount of discounts on other Organon products that Medicaid either did not purchase or that were not setting a best price. Kaiser initially rejected any revision as there was no provision for Organon to take a price increase. Kaiser offered Organon a way out of the contract in which Organon would pay all future discounts in advance to avoid continuing setting a best price. In response, Organon proposed an amendment to buy its way out of the agreement. Organon and Kaiser agreed to amend the contract by altering pricing retroactively on other drugs that had limited or no exposure to Medicaid. In order to conceal the best price violation, Organon backdated the amendment and removed transactions for Remeron from its books.

15. In addition, from 1999 to 2005, Organon intentionally or recklessly failed to maintain its membership list of 340B program "covered entities." The 340B Pricing Program allows certain non-profits and other eligible entities to receive government pricing under the Public Health Service Act of 1992. 42 U.S.C. § 256b. For six years, Organon failed to employ effective procedures that would have enabled it to properly monitor its membership list of 340B covered entities and thus avoid bestowing 340B pricing to customers who were not qualified to receive this special 340B pricing. Prices provided to

entities not qualified to receive the 340B pricing would have affected Remeron's true commercial "best price" to the private sector, but Organon failed to report these transactions at all, and after discovering the problem, Organon made no attempt to employ the necessary controls to avoid future mishaps, nor did Organon attempt to recoup discounts afforded to these ineligible entities, in effect, lowering its Medicaid rebate liability.

II. PARTIES

16. Relator James Banigan is a citizen of the United States and a resident of the State of Arizona.

17. Relator Richard Templin is a citizen of the United States and a resident of the State of New Jersey.

18. Defendant Akzo Nobel is a Netherlands corporation specializing in chemical coatings. Akzo Nobel conducts extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Akzo Nobel may be served through its registered agent, Akzo Nobel, 7 Livingston Ave., Dobbs Ferry, NY 10522.

19. Defendant Organon Biosciences N.V. was a Netherlands corporation created by Akzo Nobel in 2006 to oversee Organon USA, Inc., Organon International, Inc., and/or Organon Pharmaceuticals USA, Inc. Organon Biosciences N.V. specialized in the development, manufacture, and sale of human and animal health care products and

services, including pharmaceuticals. Organon Biosciences N.V. conducted extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Organon Biosciences N.V. may be served through its registered agent, Akzo Nobel, 7 Livingston Ave., Dobbs Ferry, NY 10522.

20. Defendant Organon USA, Inc. was a New Jersey corporation whose principal business was the development, manufacture, and sale of health care products and services, including pharmaceuticals. Organon USA, Inc.'s principal place of business was at 2000 Galloping Hill Road, Kenilworth, New Jersey 07033-0530. Organon USA, Inc. conducted extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Organon USA, Inc. was wholly owned by Organon BioSciences N.V., which was in turn wholly owned by Akzo Nobel, a Netherlands corporation specializing in chemical coatings. Organon USA, Inc. manufactured and sold prescription drugs that are paid for by state Medicaid programs, including such medications as Remeron Tablet and Remeron SolTab. Akzo Nobel announced on March 12, 2007 its intent to sell Organon Biosciences N.V. to pharmaceutical company Schering-Plough for EUR 11 billion ($14.4 billion based on the closing exchange rate on March 9, 2007). Schering-Plough finalized its acquisition of

Organon BioSciences N.V. in November 2007, and Organon Biosciences N.V. became a subsidiary of Schering Plough. Organon USA, Inc. may be served through its registered agent, Akzo Nobel, 7 Livingston Ave., Dobbs Ferry, NY 10522.

21. Defendant Organon Pharmaceuticals USA, Inc. was a Delaware corporation whose principal business was the development, manufacture, and sale of health care products and services, including pharmaceuticals. Organon Pharmaceuticals USA, Inc. conducted extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Organon Pharmaceuticals USA, Inc. may be served through its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

22. Defendant Organon International, Inc. was a Delaware corporation whose principal business was the development, manufacture, and sale of health care products and services, including pharmaceuticals. Organon International, Inc. conducted extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Organon International, Inc. may be served through its registered agent, The Corporation Trust Company, Corporation Trust Center, 1209 Orange Street, Wilmington, DE 19801.

23. Defendants Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International, Inc., and Organon Biosciences N.V. were or at pertinent times were wholly-owned subsidiaries and pharmaceutical business units of Defendant Akzo Nobel N.V.

24. Defendants Akzo Nobel, Organon USA, Inc., Organon Pharmaceuticals USA, Inc., Organon International, Inc., and Organon Biosciences N.V. are hereinafter referred to collectively as "Organon." Defendants Organon USA, Inc. and Organon Biosciences N.V. are hereinafter referred to collectively as "Organon IBS."

25. Defendant Schering-Plough is a New Jersey corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Schering-Plough conducts extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. Schering-Plough may be served through its registered agent, The Corporation Trust Company, 820 Bear Tavern Rd, West Trenton, NJ 08628.

26. Defendant Merck & Co., Inc. ("Merck") is a New Jersey corporation whose principal business is the development, manufacture, and sale of health care products and services, including pharmaceuticals. Merck conducts extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the

Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. On November 3, 2009, Merck and Schering-Plough combined in a stock and cash transaction, structured as a reverse merger in which Schering-Plough, renamed Merck, continued as the surviving public corporation. Merck may be served through its registered agent, CT Corporation, 155 Federal Street, Suite 700, Boston, MA 02110.

27. Defendant Omnicare, Inc. is a Delaware corporation whose principal business is providing pharmacy services to patients in long-term care settings. Omnicare's principal place of business is 100 East RiverCenter Boulevard, Covington, Kentucky 41011. Omnicare conducts extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. From 2001 to 2005, Omnicare, headquartered in Covington, Kentucky, systematically acquired its competitor long-term care pharmacy providers, NeighborCare, NCS Healthcare, and American Pharmaceutical Services ("APS"), a subsidiary of Mariner Health Group, making it the nation's largest provider of pharmacy services to long-term care facilities, providing pharmacy services to an estimated 1,400,000 beds in long-term care facilities and other chronic care settings. Omnicare acquired APS from Mariner in 2002, NCS Healthcare in 2003, and NeighborCare, Inc. in 2005. Upon information and belief, Omnicare is the successor-in-interest to APS, NCS Healthcare, and NeighborCare, and has assumed their rights, duties, and liabilities. Omnicare may be served through its registered agent, CSC – Lawyers Incorporating Service, 421 West Main, Frankfort, KY 40601.

28. Defendant PharMerica, Inc. is a Delaware corporation whose principal business is providing pharmacy services to patients in long-term care settings. PharMerica's principal place of business is at 1901 Campus Place, Louisville, Kentucky 40299. PharMerica conducts extensive business in the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. PharMerica is one of the nation's largest long-term care pharmacy providers, specializing in the provision of pharmacy supplies and services to long-term care institutions. In 1999, it provided pharmacy products and services to approximately 500,000 patients in long-term care and alternative settings, servicing an estimated 380,000 beds in skilled nursing facilities. On April 26, 1999, Bergen Brunswig acquired PharMerica, Inc. and PharMerica became a wholly-owned subsidiary of Bergen Brunswig. Bergen Brunswig then merged with AmeriSource Health Corporation on March 29, 2001 to form AmerisourceBergen. In 2006, AmerisourceBergen merged PharMerica with Kindred Healthcare Inc. to form PharMerica Long-Term Care, now headquartered in Louisville, Kentucky, allowing PharMerica to better compete with the nation's current giant of long-term care pharmacy services, Omnicare. PharMerica may be served through its registered agent, CSC-Lawyers Incorporating Service, 421 West Main, Frankfort, KY 40601.

III. RESPONDEAT SUPERIOR AND VICARIOUS LIABILITY

29. Any and all acts alleged herein to have been committed by the Organon defendants were committed by officers, directors, employees, representatives or agents who

at all times acted on behalf of their respective Organon defendant(s) and within the course and scope of their employment.

30. The Organon defendants are related entities sharing common employees, offices and business names such that they are jointly and severally liable under legal theories of respondeat superior. Further, the past, present and continuing relations and dealings by and between these related entities are so inextricably intertwined that for purposes of this suit, some or all of them can and should be considered as a single entity at law and equity.

IV. SUCCESSOR LIABILITY

31. Defendant Schering-Plough is the successor-in-interest to the Organon IBS defendants and has assumed their rights, duties, and liabilities. Schering Plough's purchase of the Organon IBS defendants has resulted in the substantial continuity of the Organon IBS defendants' business. For example, Schering Plough retained some of Organon USA, Inc.'s employees, including Carroll "Butch" McKenna, Director for Senior Care/Long Term Care for Organon USA, Inc., and now a District Manager for Schering Plough, Mike Dziomba, Vice President of Fertility for Organon USA, Inc., and now Executive Director of Sales for Schering Plough, and members of Organon USA Inc's legal counsel, Fred Figa and Jon Beck, as a result of its purchase of the Organon IBS defendants. In addition, Schering-Plough retained the Organon IBS defendants' production facilities, continued to produce the Organon IBS defendants' products, such as Remeron, and continued to use the Organon IBS defendants' name in conjunction with the Schering-Plough name. As successor-in-interest to the Organon IBS defendants, Schering-Plough has assumed Organon's liabilities with respect to this suit.

32. Defendant Merck is the successor-in-interest to the Organon IBS defendants and Schering-Plough and has assumed their rights, duties, and liabilities. Merck's purchase of Schering-Plough has resulted in the substantial continuity of Schering-Plough and the Organon IBS defendants' business. For example, upon information and belief, Merck retained some of Organon USA, Inc.'s employees, including Carroll "Butch" McKenna, Director for Senior Care/Long Term Care for Organon USA, Inc., and subsequently District Manager for Schering Plough, and members of Organon USA Inc's legal counsel, Fred Figa and Jon Beck, as a result of its purchase of Schering-Plough. In addition, Merck retained the Organon IBS defendants' and Schering-Plough's production facilities and continued to produce the Organon IBS defendants and Schering-Plough's products, such as Remeron. As successor-in-interest to Schering-Plough and the Organon IBS defendants, Merck has assumed Organon's liabilities with respect to this suit.

V. JURISDICTION AND VENUE

33. Jurisdiction and venue are proper in this Court pursuant to the False Claims Act (31 U.S.C. § 3732(a)) because Relators' claims seek remedies on behalf of the United States for multiple violations of 31 U.S.C. § 3729 in the United States by all or any one of Defendants, some of which, upon information and belief, occurred in the Southern District of Texas and the District of Massachusetts, and because, based on information and belief, all or any one of Defendants transact other business within the Southern District of Texas and the District of Massachusetts.

34. All defendants are subject to the general and specific personal jurisdiction of this Court. Defendant Akzo Nobel is a large multinational group of companies, which engages in a variety of business activities, including developing, marketing, and selling

pharmaceutical products throughout the United States and within the District of Massachusetts, all of which it accomplishes through its corporate center, business units, subsidiaries, officers, directors, employees, and agents. Akzo Nobel has a two-layer organizational structure with a corporate center and business units in Pharmaceutical, Coatings, and Chemicals, which are generally organized by location, including companies operating throughout the United States. The functions of the corporate center and the business units overlap. Akzo Nobel's corporate center coordinates "key tasks" in areas such as finance, human resources, technology, legal matters, and intellectual property. Akzo Nobel employees often rotated to and held positions at Organon USA, Inc.

35. Furthermore, Organon USA, Inc., Organon International, Inc., and Organon Pharmaceuticals USA, Inc. were mere instrumentalities and/or agents of Akzo Nobel; without them Akzo Nobel would have been forced to perform their services itself. In particular, Akzo Nobel exerted control over Organon USA, Inc. For example, the Chief Executive Officer of Organon sat on the board for Akzo Nobel and reported directly to the Chief Executive Officer of Akzo Nobel. Akzo Nobel and Organon employees often sat together on committees involving marketing and production of pharmaceuticals. The in-house legal counsel for Organon USA, Inc. received their salaries from Akzo Nobel. In addition, Organon USA, Inc. senior management obtained approval from Akzo Nobel for the marketing budgets and strategic plans for its pharmaceuticals. Organon USA, Inc. senior management was also required to obtain approval for any raises given to employees that exceeded ten percent. As a result of Akzo Nobel's organizational structure, Akzo Nobel and Organon Biosciences N.V. have continuous and systematic contacts with the United States through their contacts with their American subsidiaries.

VI. OVERVIEW OF MEDICAID, 340B AND OTHER FEDERAL HEALTHCARE PROGRAMS

A. The Medicaid Program

36. Medicaid was established by Title XIX of the Federal Social Security Act, 42 U.S.C. § 1396 *et seq.* (the "Medicaid Program"). Medicaid is a joint federal-state program that provides health care benefits for certain groups, primarily the poor and disabled.

37. The federal Medicaid statute sets forth the minimum requirements for state Medicaid programs to qualify for federal funding. *See* 42 U.S.C. § 1396a. The federal portion of states' Medicaid payments, known as the Federal Medical Assistance Percentage ("FMAP"), is based on a state's per capita income compared to the national average. 42 U.S.C. § 1396d(b). Among the states, the FMAP is at least 50%, and as high as 83%.

38. The vast majority of states award contracts to private companies to evaluate and process Medicaid recipients' claims for payment. Typically, after processing the claims, these private companies then generate funding requests to the state Medicaid program, which in turn obtains federal funds from the United States.

i. Drug Reimbursement Under State Medicaid Programs

a. Medicaid Reimbursement Formulas for Single Source Drugs

39. When paying claims for reimbursement of drugs, the state Medicaid programs' goal has been to pay an amount which, in the aggregate, reflects the lower of: (1) the estimated acquisition cost ("EAC") of covered drugs, plus a reasonable dispensing fee; or (2) a provider's usual and customary charge to the general public. To determine the EAC for a covered drug, state Medicaid programs are required to develop reimbursement

formulas that must be approved by the Secretary of Health and Human Services ("HHS"). 42 C.F.R. §§ 447.331, 447.332, 447.333 (2005).

40. The states' various methodologies for arriving at EAC throughout the relevant period have included:

(a) discounting a percentage off of the Average Wholesale Price ("AWP");

(b) adding a percentage to the Wholesale Acquisition Cost ("WAC"); and/or

(c) requiring the drug companies to certify prices directly in writing to the Medicaid program in response to state requests for particular pricing information.

41. AWP is used to refer to the price at which a pharmaceutical manufacturer or a wholesaler typically sells a drug to a retail customer, who then administers it to a patient. WAC is used to refer to the price at which a pharmaceutical manufacturer typically sells a drug to wholesalers, who then resell it to a retail customer.

42. While the majority of states use published AWPs to calculate reimbursement, nine states (Alabama, Arkansas, Colorado, Florida, Maryland, Massachusetts, Ohio, Rhode Island, and Texas) use the wholesale acquisition cost ("WAC") to set the EAC.

43. The AWPs and WACs relied upon by the state Medicaid programs are published for each drug identified by National Drug Code ("NDC"). There are several pharmaceutical industry compendia that periodically publish, in printed and electronic media, the AWPs for the tens of thousands of drugs, such as (1) Thompson Publishing, publisher of the *Red Book*; (2) First Databank, publisher of the *Blue Book*; and (3) Medi-

Span, Inc., publisher of an electronic or automated price service and the Hospital Formulary Pricing guide (hereafter referred to collectively as the "Publishers").

44. In periodically announcing the AWP and WAC for each drug, the Publishers publish the prices that are supplied to them by pharmaceutical manufacturers for their respective drugs. Thus, the AWP and WAC generally are not independently determined by the Publishers; pharmaceutical manufacturers control the prices listed as the AWPs and WACs for each drug.

b. Medicaid Reimbursement Formulas for Multi-Source Drugs

45. States use either maximum allowable cost ("MAC") or the federal upper limit ("FUL") to determine Medicaid reimbursement for multiple source drugs. States with a MAC system either use the lowest AWP for a generic version of the drug or their own formulas to determine MAC. States with MAC programs generally publish lists of generic and multi-source drugs along with the maximum price at which Medicaid will reimburse. In general, the prices on the MAC lists are lower than the FUL prices set by the federal government.

c. Long-Term Care is Dominated by Medicaid

46. Long-term care residents often arrive at a nursing home with Medicare coverage, but Medicare provides only a limited number of days of coverage. Once those days are exhausted and the resident meets the required income level by depleting his or her savings, that resident becomes eligible for Medicaid, with its accompanying prescription benefit. In the 1999 to 2005 time period, according to Organon, about 86% of nursing home residents were Medicaid-eligible, including those eligible under both Medicare and Medicaid. In contrast, managed care and cash reimbursement in 1997 comprised only 14%

of total long-term care revenue. Medicaid thus dominated the long-term care segment of pharmaceutical sales until Medicare Part D commenced in January of 2006.

B. 340B Covered Entities

47. The Public Health Service Act of 1992 established the Section 340B drug discount program. 42 U.S.C. § 256b. Under the 340B program, drug manufacturers are required to provide statutorily defined discounts on outpatient drugs to "covered entities." "Manufacturers are required to participate in the 340B program as a condition of having drug charges reimbursed by Medicaid." *County of Santa Clara v. Astra USA, Inc.*, 2006 U.S. Dist. LEXIS 57176 (N.D. Cal. July 28, 2006.

48. "Covered entities" mean federally qualified health center look-alike programs; certain disproportionate share hospitals owned by, or under contract with, state or local governments, and several categories of facilities or programs funded by federal grant dollars, including federally qualified health centers, AIDS drug assistance programs, hemophilia treatment centers, sexually transmitted disease ("STD") grant recipients, and family planning clinics. 42 U.S.C. § 256b.

C. Other Federal Purchasers

49. Drug manufacturers are required to list their brand-name drugs on the Federal Supply Schedule to receive payment for the purchase of drugs by federal agencies and under the Medicaid program. 38 U.S.C. § 8126(a)(4). The Department of Veterans Affairs negotiates Federal Supply Schedule contracts with pharmaceutical companies to establish the prices available for brand-name drugs to all direct federal purchasers, such as the Department of Defense, the Veterans' Administration, the Bureau of Prisons, and the Bureau of Indian Affairs.

VII. STATUTORY BACKGROUND

A. The False Claims Act

50. For conduct occurring before May 20, 2009, the False Claims Act ("FCA") provides in pertinent part that:

> (a) Any person who
>
> (1) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;
> (3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;
>
> ***
>
> (7) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government,

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim. 31 U.S.C. § 3729(a).

51. For conduct occurring on or after May 20, 2009, the FCA provides that any person who:

(a) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim (except that this language applies to all claims pending on or after June 7, 2008)

(c) conspires to defraud the Government by committing a violation of the FCA;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim. 31 U.S.C. § 3729(a)(1).

B. The Federal Anti-Kickback Statute

52. The Medicare-Medicaid Anti-Fraud and Abuse Amendments, known as the Medicare Anti-Kickback Statute (the "Anti-Kickback Statute"), 42 U.S.C. § 1320a-7b(b), make it illegal for an individual knowingly and willfully to offer or pay remuneration in cash or in kind to induce a physician to order a good or service that is reimbursed by a federal healthcare program. *See* 42 U.S.C. § 1320a-7b(b)(2). "Remuneration" is broadly defined to include anything of value offered or paid in return for purchasing, ordering, or recommending the purchase or order of any item reimbursable by a federal healthcare program.

53. The purpose of the Anti-Kickback Statute is to prohibit such improper remuneration, in order to secure proper medical treatment and referrals and to limit unnecessary treatment, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services.

54. Paying kickbacks taints an entire prescription, regardless of the medical propriety of its use. The kickback inherently interferes with the doctor-patient relationship and creates a conflict of interest, potentially putting the patient's health at risk.

VIII. OVERVIEW OF REMERON AND THE LONG-TERM CARE ARENA

A. Remeron: Regulatory History

55. Organon launched Remeron Tablet in August of 1996 following FDA approval of the drug for the treatment of depression in adults. The drug was billed as the first in a new class of anti-depressants called "noradrenergic and selective serotonergic anti-depressants" ("NaSA"). Remeron Tablet was manufactured in 15 mg, 30 mg, and 45 mg formulations, taken once a day.

56. According to Organon's literature, Remeron Tablet has a dual-action effect that rectifies an imbalance of the brain chemicals noradrenaline and serotonin, both of which are believed to be involved in causing depression. Remeron Tablet is believed to exert its therapeutic effects by increasing the release of both of these neurotransmitters from nerve cells in the brain, thereby correcting the deficiencies and relieving depressive symptoms such as depressed mood.

57. Organon's patent for Remeron Tablet, first issued in 1977, expired on June 14, 1998, with generic manufacturers expected to enter the market as early as May 2001. Organon's managers saw the expiration of Remeron Tablet's patent as a potentially cataclysmic event for the company, likely resulting in significant layoffs. As Remeron SolTab was launched in 2001 in the hopes of maintaining Organon's Remeron market share in the face of generic competitors, and anxiety rose among Remeron managers, the company's culture increasingly supported a willingness to preserve Remeron business, whatever the means.

58. Organon undertook two actions to prevent the perceived disaster. First, on November 2, 1999, Organon obtained a new patent that purported to claim a combination

therapy of mirtazapine together with a selective serotonin reuptake inhibitor ("SSRI"), which effectively blocked generic competitors' entry to the marketplace until February of 2003. A patent infringement suit and a related case against Organon brought by generic manufacturers ensued, with the latter case finally settling in August of 2005.

59. Second, Organon submitted a new drug application to the FDA for a variant form of Remeron: an orally disintegrating tablet called Remeron SolTab, available in the same dosages as the tablets. Organon trumpeted Remeron SolTab as improving "patient compliance," particularly in long-term care, because it could be administered without water. The FDA approved the new Remeron product on January 12, 2001. Because Remeron SolTab was not initially rated as AB equivalent to Remeron Tablet, generic competitors were barred from manufacturing a similar mirtazapine orally-disintegrating tablet. Organon's creation of Remeron SolTab made it possible to not only maintain market share through conversion to the patent-protected product, but to continue to expand the business. At the core of Organon's brand strategy for Remeron after the launch of Remeron Soltab was the achievement of those twin goals through a bevy of illegal kickbacks of different kinds.

B. Remeron Sales to Long-Term Care

60. Remeron has never been among those anti-depressants that have attained "household name" status such as Prozac, Paxil, or Zoloft. Its selling points—a short half-life and unproven, unapproved claims of avoidance of side effects such as insomnia and anxiety—had apparently not proved compelling enough to health care providers at large. Remeron, however, has had one, very lucrative niche: *long-term care*. While Remeron products made up less than 5% of the overall market share for anti-depressants during the

relevant period, they made up 15% percent of anti-depressant sales to long-term care pharmacies—a three-fold increase in market share. From 2000 to 2004, as much as 35% of Remeron's total sales were derived from prescriptions for residents of long-term care facilities. These pharmacies had powerful financial reasons to prefer Remeron, as described below.

61. As Organon noted in its 2000 Training Manual for Long Term Care ("LTC Sales Manual"), in recent years the senior care marketplace has been the fastest-growing segment of the healthcare industry for pharmaceutical sales, as the growing elderly population has created a rapidly rising demand for long-term care services.

62. Most "skilled nursing facilities," or nursing homes, contract with "long-term care pharmacy providers" ("LTCPPs"),[1] which are institutional pharmacies specializing in the skilled nursing facility ("SNF") market. Some nursing homes have their own in-house pharmacies, while many others contract with nationwide corporate pharmacy providers. In 1999, as Organon's LTC Sales Manual explained, the top five corporate long-term care pharmacy providers accounted for over 50% of all U.S. nursing home residents:

Company	Number of SNF Beds Serviced
Omnicare	578,000
PharMerica	380,000
NeighborCare	248,000
NCS	248,000
Living Centers of America	101,000

63. By 2001, according to a Remeron business plan authored by Organon managers John Maddox and Butch McKenna ("Business Plan"), the seven largest LTCPPs

[1] Organon refers to long term care pharmacies such as PharMerica as "pharmacy providers," and thus uses the acronym "LTCPP," but they are also known as "LTCPs," long term care pharmacies.

accounted for almost 77% of skilled nursing facilities and 72% of total skilled nursing facility beds:

LTCPP	# SNFs	# Beds	# SNFs	# Beds	% SNFs	% Beds
NeighborCare	2,100	211,500	17,176	1,848,293	12.2%	11.4%
PharMerica	2,850	287,760	17,176	1,848,293	16.6%	15.6%
Omnicare	5,000	495,000	17,176	1,848,293	29.1%	26.8%
NCS	1,875	188,100	17,176	1,848,293	10.9%	10.2%
APS	430	50,000	17,176	1,848,293	2.5%	2.7%
Vencare	325	32,000	17,176	1,848,293	1.9%	1.7%
Sunscript	600	56,800	17,176	1,848,293	3.5%	3.1%
TOTAL	**13,180**	**1,321,160**	**17,176**	**1,848,293**	**76.7%**	**71.5%**

64. In order to buy the drugs they disburse to residents, long-term care pharmacies generally contract with one of the following: (1) a long-term care buying group; (2) a group purchasing organization ("GPO"); or (3) the pharmaceutical company itself. Among the most prominent GPOs are Managed Healthcare Associates, Inc. ("MHA"), based in East Hanover, New Jersey, GeriMed, based in Louisville, Kentucky, and Committed Provider Services, an alliance between Bergen Brunswig Drug Company, NCS Healthcare, and Tenet BuyPower. Together, in 2001, these GPOs represented over 90% of Remeron Tablet and Remeron SolTab prescriptions filled in long-term care. By 2000, however, Organon had begun the process of negotiating direct contracts with the largest long-term care pharmacy providers—PharMerica, Omnicare, NCS Healthcare, NeighborCare, APS and Sunscript, as described in Section IX.

IX. ORGANON'S SCHEME TO DEFRAUD MEDICAID BY OFFERING FINANCIAL INDUCEMENTS TO LONG-TERM CARE PHARMACY PROVIDERS TO PURCHASE AND RECOMMEND REMERON TABLET AND REMERON SOLTAB

A. Organon's Kickbacks to Long-Term Care Pharmacy Providers from 1999 to 2000

65. Carroll "Butch" McKenna, Director for Senior Care/Long Term Care, and John Maddox, Manager for Senior Care/Long Term Care, both within Organon's National Accounts Division, handled much of the contracting with the large long-term care chains and pharmacy managers. McKenna later disclosed to Relator Banigan in private conversation that, beginning in 1999, Remeron Tablet sales were driven in large part by market share discounts and rebates meant to induce pharmacies to recommend Remeron over competitors, regardless of physician recommendations.

66. Beginning in late 1999, Organon entrusted the marketing of Remeron in the long-term care sector and the negotiation of long-term contracts with long-term care pharmacy providers—not to its normal sales force of about 500 Remeron sales representatives, but to a special, more discreet group of about twenty regional account managers specializing in long-term care, called Long Term Care Sales Specialists or Senior Care Regional Account Managers ("SCRAMs"). In fact, normal field representatives were not permitted to call on long-term care facilities at all. Long-term contracts arising out of this specialized sales force's calls were approved by a contract review committee, which was chaired by the Vice President of Marketing and the Executive Director of Managed Markets, both of whom were members of Organon's Executive Leadership Team.

67. Until 1999, Organon negotiated only modest discounts, with 2% going to long-term care members of the GPOs and another 2% to 3% in administrative fees paid to the GPOs based on members' Remeron purchases. These discounts arguably fell under a limited Anti-Kickback Statute exemption for small, fixed GPO discounts. *See* 42 U.S.C. § 1320a-7b(b)(3); 42 C.F.R. § 1001.952(j).

68. In 1999, in addition to GPOs' relatively modest discounts, Organon began offering Remeron contract terms that included much larger discounts and rebates of various kinds on Remeron Tablet applicable only to the long-term care pharmacy provider members of these GPOs. Organon executives hoped that running the contracts through the GPOs would shield the kickbacks from the government's disapproval of financial incentives to pharmacies.

69. Organon's 1999 and 2000 contracts with the most prominent GPOs, such as GeriMed, Managed Healthcare Associates, Owen and Committed Provider Services, provided long-term care pharmacy provider members with **8% to 14.8% "ramp-up" charge-back discounts** for the first five months, followed by **8% to 15% chargeback discounts** after that, depending on the market share held by Remeron Tablet for that member of the GPO. These market-tier discounts were based on the performance of individual long-term care pharmacy providers, not the performance of the GPO as a whole. In exchange for these discounts, Organon required the long-term care pharmacy providers to promote Remeron Tablets to their individual pharmacies. This scheme was highly successful; long-term sales increased, making Remeron Organon's largest-selling product. These contracts remained in place until the beginning of 2001, when Organon began entering into contracts directly with long-term pharmacy providers, except for NeighborCare and NCS Healthcare, bypassing the GPOs.

70. Organon singled out long-term care pharmacies for discounts because long-term care pharmacies wield a powerful influence over the choice of drugs used in long-term care facilities. Upon entering a nursing home, a resident generally severs his or her ties to a family physician and falls under the care of a physician responsible for the

particular facility, who generally visits the facility every thirty days. Nurses and other facility staff who see the patient daily become the physician's influential "eyes and ears," in close consultation with the pharmacy's consultant pharmacist and clinical pharmacy staff.

71. Because long-term care pharmacy providers could exert considerable control over the drugs prescribed to nursing home residents, Organon, in marketing drugs in the long-term care arena from 2000 to at least 2004, focused on "key decision-makers" within each long-term care pharmacy provider, such as regionally-based clinical staff, consultant pharmacists, Directors of Pharmacy Operations, or Purchasing Directors, rather than physicians.

72. Organon put it this way in its LTC Sales Manual:

> Field sales personnel have traditionally focused primarily on direct physician interaction. Now, successful sales calls in the long-term care market include other important decision-makers who may influence physician prescribing practices. These include pharmacy provider personnel, consultant pharmacists, nurses, medical directors, and SNF administrators. Your knowledge of the long-term care market and the roles and responsibilities of key decision-makers will give you a competitive advantage.

B. Organon's 2000 to 2005 Scheme to Defraud Medicaid by Offering Kickbacks to Long-Term Care Pharmacy Providers

73. In mid-2000, in anticipation of Remeron SolTab launch in January 2001, Organon executives began collecting detailed data about competitors' pricing and developing a campaign to convince LTCPP's to embrace the new drug and help drive conversion from Tablet to SolTab, as well as expand market share. In carrying out this research, executives realized that Organon was well-positioned to market the "opportunity to profit" from Medicaid on Remeron SolTab. Remeron SolTab was set to be priced to be

less expensive than many anti-depressants. Indeed, Zoloft was one of the few name-brand anti-depressants with a lower AWP. With anticipated rebates available to long-term care customers factored in, Remeron could boast a superior reimbursement to long-term care pharmacies,

74. With that powerful financial incentive in their tool belt, Organon executives prepared for the first time to negotiate full-blown therapeutic interchange programs with all of the major LTCPPs. That year they prepared a Long Term Sales Training Manual ("LTC Sales Manual"), which instructed Organon's LTC sales force that long-term care pharmacy providers work directly with regional long-term care consultant pharmacists and medical directors to set up such therapeutic interchange and switch programs "in an effort to contain costs and maximize profits."

75. What pharmacy providers care about, Organon assured its sales force, was a pharmaceutical product's "spread," and its effect on "maximiz[ing] profit." LTC Sales Manual. The "spread" is the difference between the actual selling price and the reimbursement from the state Medicaid programs. "Spread may be a critical component in selecting preferred products within a therapeutic category," Organon noted in its LTC Sales Manual.

76. The LTC Sales Manual also explained to sales representatives that "enhancements may be used to win favorable contracts with providers," including up-front discounts and "rebates contracts based on segment-share performance." The LTC Sales Manual noted that "value-added programs and services may be offered to enhance the interactions between pharmacy providers and their SNF customers," such as educational

symposia for physicians and nurses, pharmacy in-services programs, market research, clinical research, support for clinical programs and therapeutic interchange programs.

77. "Therapeutic interchange" and "switch" programs can operate in different ways and bear different labels, but in essence, a long-term pharmacy has several devices at its disposal for affecting a change in drug choice among its patients. In "collateral practice" states, it can ask physicians serving its patients to sign agreements ceding their authority to choose what drug will be prescribed within a particular class. Where collateral practice is not permitted, it can attempt to persuade physicians to write new prescriptions to move patients to the preferred drug, or, under either legal or illegal circumstances, it can simply set up its computer system so that only the preferred drug may be dispensed by the pharmacist. The latter device is often called an "NDC lock." When a lock is put in place to effect a switch that requires a new prescription, as was the case in non-collateral practice states to switch a patient to Remeron SolTab from either Remeron Tablet or from another drug, in order to keep the patient medicated, a pharmacist must immediately obtain that prescription. When that is not possible, the risk that falsification will occur and even be endorsed by the company runs high.

78. In any case, therapeutic interchange and switch programs sponsored by pharmaceutical manufacturers put long-term care facility patients at risk for serious health issues. All medications within a therapeutic class are not created equally. Each drug affects each patient differently based on a multitude of factors, including other medications a patient is currently taking and other conditions that the patient may have. What is the "preferred" drug of choice from a physician's standpoint may not be the same as the drug chosen by a long-term care pharmacy provider to be the provider's "preferred" drug within

a therapeutic class. The American Medical Association has stated that "switching of therapeutic alternates in patients with chronic disease who are stabilized on a drug therapy regimen should be discouraged." AMA Policy H-125.991(2). This is particularly true in the case of long-term care patients, the majority of whom are elderly and have been on the same medications for years. Moreover, switching patients' medications often requires pharmacists to convert dosages as the medications usually come in different dosage forms. This conversion is not an exact science, leaving room the possibility that a patient may receive too little or too much medication as a result of the change.

79. Engaging in active therapeutic interchange programs that switch elderly long-term care patients from a competitor anti-depressant poses a risk of harm for these patients. The FDA-approved labeling for both drugs includes warnings that use of Remeron and Remeron SolTab may result in somnolence (drowsiness), increased appetite or weight gain, and even anxiety. The FDA-approved labeling for Remeron SolTab also notes that caution should be used in treating geriatric patients with Remeron SolTab because elderly patients often have decreased renal function making it less likely to rid their bodies of the drug. The labeling further advises that sedating drugs, like Remeron SolTab, may "cause confusion and over-sedation in the elderly." Thus, switching an elderly patient to Remeron for the sake of financial rather than clinical concerns exposes that patient to potential harm. Where the financial benefit comes out of Medicaid's pockets rather than any true cost savings, "therapeutic interchange" is unscrupulous as well.

80. Nevertheless, in late 2000, Organon began negotiating directly with the largest long-term care pharmacy providers—PharMerica, Omnicare, NeighborCare, NCS Healthcare and Sunscript. In addition to the market-share discounts and rebates, Organon

offered these providers new incentives—a "conversion rebate" up to 3% for converting prescriptions from Remeron Tablet to Remeron SolTab and a "1.5% therapeutic interchange bonus" for making Remeron "preferred" and instituting an active therapeutic interchange program that encouraged changing prescriptions from competitor antidepressants to Remeron Tablet and upon launch to Remeron SolTab.

81. Then, after Remeron SolTab's launch, Organon began reducing discounts and rebates on Remeron Tablet and offered extra incentives to convert prescriptions from the old to the new Remeron product, including a "conversion rebate" and a "therapeutic interchange bonus." At this time, Organon shifted its contracting strategy, moving toward contracting directly with long-term care pharmacy providers. As the Business Plan demonstrates, Organon planned to use some of the money from the eliminated administrative GPO fees to fund its illegal kickback scheme. *See, e.g.,* Business Plan, Exhibit 2, p. 12. Organon's direct contracting campaign was highly successful, although at least one long-term care pharmacy provider, NCS Healthcare, preferred to continue contracting through GPOs

82. .In addition, Organon increasingly moved away from price discounts, which benefit the purchaser at the time of purchase, and toward rebates, which are paid back to the purchaser later and thus are not revealed in the invoice. Organon LTC leadership requested the shift; Long Term Sales management Butch McKenna and John Maddox explained to their superiors that their long-term care customers preferred rebates over discounts as their Medicaid contracts were quickly transitioning from AWP-based reimbursement to Estimated Acquisition Cost (EAC). Under EAC regimes, Medicaid states would frequently request disclosure of pharmacists' actual contracts on claims for

reimbursement. Because rebate payments could be calculated only after the fact and rebate amounts did not appear in the parties' purchase invoice, long-term care pharmacy providers were able to hide their actual acquisition costs from state Medicaid agencies by moving from discount to rebate. McKenna referenced the need to transition to rebate payments in his 2001 Business Plan, stating: "States are undergoing major changes in Medicaid reimbursement which can affect Remeron SolTab sales. Contract strategy may need changing due to states going from AWP to Acquisition costs."

83. A February 1, 2002 internal Organon memorandum from John Ocejo to Sam Michini summed up the contract changes contained in new agreements that had recently been negotiated with three of the four GPOs:

- Aggressive ramp-ups that applied only to Remeron SolTab;
- All Remeron Tablet incentives were eliminated, including the administrative fee;
- An increased administrative fee on Remeron SolTab;
- Financial incentives changed from predominantly discounts with a small added rebate to mainly rebates with a small discount; and
- Market tier rebates that demanded high market share and conversion rates to maintain the same price as during ramp-up.

84. Organon also enticed long-term care pharmacy providers to purchase and recommend Remeron Tablet and Remeron SolTab by offering kickbacks in various forms, including data sharing agreements, research and educational grants, sponsorship of annual meetings and continuing education programs, payments for advertising initiatives, offers of nominally-priced Remeron product, entertainment, gifts and other inducements.

85. In exchange for all of these incentives, Organon sought the fullest possible "therapeutic interchange" programs to both convert Remeron Tablet scripts to Remeron

SolTab, and to expand Remeron's market share compared with other anti-depressants on formulary. Such initiatives could include "educational" programs targeting consultant pharmacists such as newsletters and in-services, internal advertising, letter-writing campaigns to physicians seeking authority to change prescriptions, and systems-based initiatives up to and including NDC locks. On an LTCPP-by-LTCPP basis, Organon was able to win commitments to undertake many of these promotional efforts, especially with regard to conversion, driving significant sales that would not have occurred if Remeron's clinical attributes had been determinative. Long-term sales continued to increase steadily with the implementation of this scheme, maintaining Remeron's status as Organon's single largest-selling product.

C. Marketing Strategies and Tools

86. In selling the long-term care pharmacy providers' "opportunity to profit" through market share rebates and discounts, conversion rebates and a bonus for actively engaging in a therapeutic interchange program, the sales team used various tools to help them, including a notebook entitled "Remeron SolTab Therapeutic Interchange Toolkit," accompanied by branded PowerPoint presentation and financial modeling tools meant to calculate to what extent long-term care pharmacy providers could enrich themselves by increasing the number of Remeron prescriptions they filled. Some of these important tools are described in more detail below.

i. 2001 Business Plan for Selling Remeron to Long-Term Care

87. In early 2001, just as Remeron SolTab was launched, Carroll "Butch" McKenna, Director for Senior Care/Long Term Care, and John Maddox, Manager for Senior Care/Long Term Care, within the National Accounts Division, eager to convert

Remeron Tablet market share in the Long Term Care segment to Remeron SolTab, created a "Business/Strategic Plan" ("Business Plan"), attached as Exhibit 2. That plan described Remeron's long-term care market share, main competitors, and main customers, discussed Medicaid as the major payor in this segment, and set the goal of converting 60% of Remeron prescriptions in the long-term care segment to Remeron SolTab by April 1, 2002, while simultaneously increasing overall Remeron sales by 20%. Business Plan, Exhibit 2, p. 5. The Business Plan laid out charts listing specific strategies for accomplishing those goals with regard to major customers Omnicare, PharMerica, NeighborCare, NCS Healthcare, Sunscript, Owen, MHA, and GeriMed, including specific ways to funnel money to these customers in exchange for increasing Remeron conversion and/or implementing a therapeutic exchange program.

88. The Business Plan reveals that Organon long-term care managers were aware that Medicaid was the dominant payor for most long-term care Remeron prescriptions in that area of health care, and purposefully marketed to pharmacies the profits to be made from Medicaid reimbursement at Medicaid's expense. The Business Plan noted, for instance:

> States are undergoing major changes in Medicaid reimbursement which can affect Remeron SolTab sales. Contract strategy may need changing due to states going from AWP to Acquisition costs.

Business Plan, Exhibit 2, p. 4. This aspect of the business plan coincided with Organon's shift to off-invoice rebates.

89. In addition, the Business Plan named as one strategy to implement that Organon LTC sales representatives be trained to use a "Profit Calculator," to show pharmacies their potential profit from Remeron scripts. Business Plan, Exhibit 2, p. 6.

Further, the Business Plan demonstrates the involvement in the Medicaid scheme of high-level Organon management and teams including Legal and Contract Development, all to be repeatedly consulted in developing strategies for selling Remeron to long-term care pharmacy providers. Business Plan, Exhibit 2, p. 5.

90. Another strategy proposed in the Business Plan was the creation of materials to assist long-term care pharmacy providers to implement a "therapeutic interchange" to authorize the conversion of Remeron Tablet prescriptions and other prescriptions to Remeron SolTab. Business Plan, Exhibit 2, p. 7. The proof that Organon management did indeed approve McKenna's and Maddox's business plan is the finished therapeutic interchange "Toolkit" itself, which is described below.

ii. The "Remeron SolTab Therapeutic Interchange Toolkit"

91. It was after Remeron SolTab was launched in January 2001 that Organon's Marketing Department hired pharmacist Dana Saffel to speak as a paid consultant covering both clinical and financial topics. As a part of her employment, Saffel also designed formal marketing materials targeting long-term care pharmacy providers' "opportunity to profit" from Organon's "attractive market share-based contract" with rebates for conversion and implementation of therapeutic interchange program for Remeron SolTab, coupled with the new product's "spread". The notebook that she helped to create, "Remeron SolTab Therapeutic Interchange Toolkit" ("Toolkit") and its accompanying CD and "Profit Calculator," makes visible and undeniable Organon's marketing practices. It is the "smoking gun" that demonstrates beyond any doubt that Organon specifically marketed to long-term care pharmacy providers the opportunity to profit illegally from Remeron prescriptions at Medicaid's expense. In 2006, when the

advent of prescription eligibility under Medicare Part D finally rendered such marketing obsolete, Organon management was eager to bury such evidence of its longtime marketing practices in long-term care. Relators nevertheless obtained a copy of the notebook, previously attached as Exhibit 1 to Relators' Original Complaint. Relators specifically retain and adopt Exhibit 1 from Relators' Original Complaint and incorporate it in this Second Amended Complaint for all purposes.

92. These printed materials were widely used by the Organon Long Term Care sales force as the primary tool for selling to both long-term care clinicians and long-term care pharmacy consultants. Dana Saffel's cover letter to the notebook made plain that the Toolkit was designed, not to be used by Organon salespeople, but to be used by long-term care pharmacy providers themselves in driving conversion and implementing a therapeutic interchange program. The cover letter named two purposes for the notebook: to persuade the pharmacy provider why it should choose Remeron SolTab as its "preferred anti-depressant agent for a large percentage of your frail elderly patients," and to teach the pharmacy provider how to "implement a therapeutic interchange program" that would successfully promote the preferred drug to patients' prescribers. Toolkit, Exhibit 1, Cover Letter, p. 1.

a. Organon's Toolkit Promoted Remeron's Sedative Qualities and Convenience for LTC Administrators in the Name of "Therapeutic Efficacy"

93. Section I of the Toolkit was devoted to Remeron's "therapeutic efficacy," aimed at providing long-term care pharmacy providers with purported scientific and medical reasons to justify Remeron as preferable to other antidepressants, even though Organon's representations about Remeron's therapeutic efficacy, such as Remeron's

sedative, anti-anxiety and weight gain qualities, were false, misleading and amounted to off-label promotion. In addition to discussing Remeron's pharmacological properties, the section discussed costs to Medicaid and convenience in administering and storing the drug. For example, on page 41, the Toolkit suggested that the "most appropriate" anti-depressant for nursing home resident is one that, among other qualities, "improve[s] reimbursement under PPS" for the resident's care by elevating the patient's reimbursement level and "reduce[s] staff time required for care."

b. Organon's Toolkit Advised LTC Customers to Adopt Remeron as Their Preferred Anti-Depressant Based First and Foremost on Their Opportunity to Profit at Medicaid's Expense

94. Section II of the Toolkit, entitled "Contract Evaluation," spelled out the bottom line for pharmacy providers: the opportunity to increase profits by encouraging the prescribing of Remeron. This section, focused on pharmacy providers' "Opportunity to Profit" based on the "spread" and the rebates and discounts offered. Section II noted that long-term care pharmacy providers should consider four primary components when they evaluate contracts: AAC (actual acquisition cost), AWP or WAC (cost to payor), Rebates & Discounts, and the cost of potential adverse drug reactions. Toolkit, Exhibit 1, Section II, p. 1.

95. In explaining to pharmacy providers how to determine their "Opportunity to Profit," Section II explicitly described Medicaid's reimbursement formulas based on AWP and WAC, then devoted a page to defining "spread" as the difference between Medicaid's reimbursement amount and the pharmacist's acquisition costs, taking into account any discounts or rebates provided for by contract. On page 17, entitled "Ethics and Morality," the Toolkit counseled:

> Pure profit alone can never be the sole deciding factor on which drug should be preferred. Contracting evaluations should always favor the drug that offers:
>
> - the highest spread for the pharmacy
> - the lowest AWP cost to the payor
> - the highest benefit to risk for the patient.

Toolkit, Exhibit 1, p. 17. On the next page, the Toolkit then proclaims Remeron SolTab as the best choice because:

> Remeron® SolTab™ provides:
> * The best spread antidepressant choice for the pharmacy
> * One of the lowest AWP costs per day for the health care payor
> * An excellent benefit to risk in depressed patients who are also experiencing anxiety, insomnia, or weight loss
> * An average "Opportunity for Profit" of $0.38/day over all the other commonly prescribed antidepressant drugs

Toolkit, Exhibit 1, p. 18.

96. The remainder of Section II was devoted to assisting the pharmacy provider in assessing the most important factor: its own "opportunity to profit" from promoting Remeron scripts. Pages 4 and 5, entitled "$pread Comparison$," compared different anti-depressants' spreads, excluding discounts, and highlighted Remeron's and two other drugs' spreads as "favorable." The Toolkit defined "opportunity to profit" as the "extra" profit a pharmacy realizes when a preferred drug with a bigger spread is prescribed instead of another drug in the same therapeutic class. *See* Toolkit, Exhibit 1. It then went on to describe various discounts and rebates available during that time, including an initial 2% discount off Remeron's WAC price, a limited-time 14% ramp-up rebate, and a range of rebates based on market share to be available after the ramp-up. Toolkit, Exhibit 1, Section

II, p. 6. The Toolkit advised that: "When maximum rebates are obtained, the new REMERON® SolTab™ market share-based contract will provide a maximum spread of $0.82/tab, making REMERON® SolTab™ very attractive in terms of spread and pharmacy profits, while offering cost savings to the payor with a low AWP and need for less adjunctive medications." Toolkit, Exhibit 1, p. 6.

97. In choosing a preferred anti-depressant, customers were urged to consider also cost savings stemming from Remeron Tablet and Remeron SolTab's supposed ability to treat other conditions, such as anxiety, weight loss, and insomnia, as well as depression, possibly eliminating the need for a second prescription. For example, in the guise of allaying fears that a pharmacy will lose money if it substitutes Remeron SolTab for an anti-depressant that is prescribed in combination with an anti-anxiety drug, the Toolkit seized the opportunity to warn that Medicaid reimburses for generic drugs at very low prices, sometimes less than the administrative costs of disbursing and administering them. Toolkit, Exhibit 1, Section II, pp. 15-16. The Toolkit stated:

> The Impact of MAC
> - Drugs that are MAC'd offer substantially lower GPs [Gross Profits]
> - REMERON® SolTab™'s (RST) OFP [Opportunity for Profit] over SSRI more than compensates for the lost prescription revenue of MAC'd drugs.

Toolkit, Exhibit 1, p. 16. The Toolkit further emphasized Remeron's opportunity for profit by claiming that Remeron SolTab showed a net gain from $0.24 to $0.32 when an SSRI and other generic drugs are discontinued. Toolkit, Exhibit, p. 16.

98. A customer is therefore better off disbursing a name-brand, single-source drug like Remeron SolTab than a generic anti-depressant.

99. If, however, the customer receives similar discounts and rebates under contracts with other anti-depressants, calculating which drug provides the greatest profits requires a little more work, the Toolkit pointed out. Toolkit, Exhibit 1, Section II, p. 7. It therefore provided a convenient worksheet for comparing AWP, acquisition costs, spread, rebates, gross profits, and opportunity to profit for each drug in Remeron's therapeutic class, with the AWP already filled in. Toolkit, Exhibit 1, Section II, p. 11-13. In addition, the manual was accompanied by a branded electronic diskette titled with the same name ("Toolkit CD") that housed a financial model meant to encourage long-term care customers to calculate even more easily their relative spread and profit.

c. Organon's Toolkit Showed LTC Customers Exactly How to Control Which Anti-Depressant Was Prescribed to Their Disabled and Elderly Patients

100. Organon hired pharmacist Dana Saffel for the specific purpose of developing a set of materials for pharmacy providers to use to convert prescriptions to Remeron SolTab from both Remeron Tablet and other anti-depressants. Section III of the Toolkit includes step-by-step directions for "implementing a therapeutic interchange" using both the Remeron drug information in Section I, in addition to a full portfolio of materials she developed for that purpose. These materials were also included on the accompanying CD as templates.

101. The Toolkit CD advised that a pharmacy could reach the maximum market share attainable for a preferred drug in three to six months. It laid out a timeline that began with planning and moved on to physician notification, "point-of-disbursing intervention," and monitoring. As the Toolkit CD pointed out, converting prescriptions is simple under a "collaborative practice agreement," in which a physician broadly authorizes

a pharmacist to initiate, change, discontinue, and/or monitor patient medications. Some long-term care facilities incorporate such an agreement into their policies and procedures. Where this exists in its broadest form, the only communication to a physician is a notification of the change.

102. As an alternative, the Toolkit CD suggested a subtler method for obtaining physician authorization. In a typical long-term care facility, a physician signs orders for his or her patients on a monthly basis. The Toolkit recommended including a broad "authorization phrase" on this Physician's Order Summary such as:

> "May use alternate dosage form of ordered drug if necessary and appropriate" (would allow conversion from Remeron Tablet to Remeron SolTab);
> or
> "May perform therapeutic interchange on appropriate drugs per facility policy" (even broader)

That way, the Toolkit CD suggested that "[o]nce the physician has signed the monthly orders, he has authorized the activity."

103. The Toolkit CD included these template "tools" for increasing Remeron SolTab's market share:

- **Introductory letter to physicians:** Extols virtues of Remeron, with attached chart of applicable patients and authorization and clinical studies.

- **Memorandum to facility administrators announcing Remeron SolTab as preferred drug:** Focusing on efficiency, convenience, regulatory issues, states that pharmacy "will be identifying those residents who may benefit from Remeron SolTab as we visit your facility and will be making appropriate recommendations to the attending physician."

- **Announcement to Facility Staff:** States that "[a]ll Remeron orders will be converted to this new and easy to administer dosage form."

- **Several example prescriptions to insert in consulting pharmacists' patient-specific recommendations:** To move resident to Remeron SolTab from Remeron Tablet or other anti-depressants. For different indications, including swallowing problem, anxiety, weight loss, insomnia, "administrator's slant" and "director of nursing slant." The Toolkit CD suggested adding boxes for yes or no for the physician to check.

- **Point-of-disbursing intervention forms:** "Clinical alerts" to send to physicians when a refill order is received or when a physician defies earlier requests and writes a new prescription for a non-preferred drug, asking for permission to convert the prescription to Remeron SolTab. The Toolkit CD also recommended at this point calling facility staff to win their support, then calling the physician.

104. In Section III, the Toolkit actually hypothesized that, if five pharmacists each spent one overtime day calling 11 physicians an hour, spending five minutes on each call, they could convert 444 prescriptions at labor costs of only $2,500 and still save over $56,000 every month by converting to Remeron SolTab.

105. The Toolkit makes abundantly clear just how much influence pharmacists have over what product is prescribed to long-term care residents of their facilities, and just how much profit is at stake when they wield that influence.

D. Organon's Offer of and Long-Term Care Pharmacy Providers' Solicitation of Kickbacks

106. From 1999 through 2005, to expand and maintain its market share for its drugs Remeron and Remeron SolTab, Organon offered kickbacks in various forms to LTCPPs, such as PharMerica, Omnicare, NeighborCare, NCS Healthcare, APS, and Sunscript, all for the purpose of inducing LTCPPs to purchase Remeron Tablet and Remeron SolTab and often in exchange for bestowing Remeron Tablet and Remeron SolTab with a "preferred" status and engaging in an active therapeutic interchange

program. For example, Organon offered deep discounts and rebates on Remeron and Remeron SolTab, such as ramp-up discounts, market share discounts and rebates, "conversion" rebates, and "therapeutic interchange" bonuses. Organon's kickbacks also took the form of data sharing agreements for the purchase of LTCPP prescribing data, research grants, educational grants, access fees, sponsorship of long-term care pharmacy providers' annual meetings, advisory panels, and other forms of remuneration. All of these financial incentives were done at the expense of Medicaid and other federal healthcare programs.

i. PharMerica

107. PharMerica is one of the nation's largest long-term care pharmacy providers and Organon's largest customer. In 1999, Organon contracted directly with PharMerica, providing an initial discount of 5% for the first five months of the contract period, followed by 2% to 9% discounts after that, dependent on Remeron's market share for that member. In late 2000, anticipating FDA approval of Remeron SolTab, Organon approached Bergen Committed Provider Services, a GPO of which PharMerica was a member, to negotiate a contract for the purchase of Remeron Tablet and Remeron SolTab by PharMerica. Organon offered a **12% ramp-up discount through September 30, 2001 and a 5% to 12% chargeback discount** after that based on market tier. The contract also included a **1.5% therapeutic interchange bonus and a conversion rebate of up to 3%** for prescriptions converted from Remeron Tablet to Remeron SolTab available only to long-term care members of Committed Provider Services. Upon information and belief, PharMerica agreed to give Remeron "preferred" status and implement a therapeutic interchange program.

108. In March 2002, Organon contracted directly with PharMerica, changing the discounts to rebates. The March 2002 contract increased the ramp-up rebate to 14% and extended this rebate through September 30, 2002. In June 2002, Organon and PharMerica amended the contract to add a conversion rebate. PharMerica could earn up to 10% of its Remeron Tablet purchases if its Remeron SolTab purchases comprised at least 90% of its total Remeron purchases, and 8% of its Remeron Tablet purchases if its Remeron SolTab purchases comprised between 80% to 89% of its total Remeron purchases.

109. Through several contract amendments, Organon continued to offer the 14% ramp-up rebates, conversion rebates, therapeutic bonuses, and market-share rebates in various forms provided to PharMerica until December 31, 2005. Organon pricing data for PharMerica demonstrates that PharMerica received these rebates until 2005.

110. In 2001, in addition to offering kickbacks in the form of market-share discounts and rebates, conversion rebates, and therapeutic interchange bonuses to PharMerica, Organon offered other kickbacks to PharMerica in various forms in exchange for pushing conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions and implementing a therapeutic interchange program. These kickbacks included, but were not limited to, data sharing or data purchasing agreement, meeting sponsorships, in-service programs, advisory boards, offers of nominally-priced Remeron SolTab, advertising initiatives, entertainment, gifts, and other inducements. For example, the 2001 Business Plan proposed by Maddox and McKenna recommended budgeting for data purchase from PharMerica, noting that "Purchasing data and increasing level of Support is helping ... convert and increase utilization of Remeron SolTab." Business Plan, Exhibit 2, pp. 10-12.

The 2001 Business Plan also set aside money for educational mailings, providing educational and clinical services, in-service programs, $15,000 to sponsor PharMerica's annual meeting, conversion letters, inclusion in advertising boards, mailings, letters and conference calls. Business Plan, Exhibit 2, pp. 10-12.

111. In late 2000 and early 2001, once Organon expressed interest in therapeutic interchange and a willingness to back up the commitment with cash, PharMerica actively pursued Organon to participate in its Vendor in Partnership ("VIP") program, which was little more than a conduit to funnel money to PharMerica in exchange for Remeron prescriptions. PharMerica used the program as an internal ranking system to reward pharmaceutical manufacturers, including Organon. PharMerica ranked pharmaceutical manufacturers according to the amount of "rebate discounts" on their drugs and the amount of "contributions" (essentially cash gifts) these companies made to the vendor in partnership ("VIP") program at PharMerica. The VIP program had different levels of achievement, with Diamond Level being the highest a company could reach. In order to reach Diamond Level, a pharmaceutical company would have to contribute at least $150,000 per product to the VIP program. With recognition in the VIP program, a pharmaceutical company would receive additional support from PharMerica in implementing therapeutic interchange programs and other sales initiatives.

112. PharMerica would also choose a Vendor of the Year from the various high-ranking pharmaceutical manufacturers participating in the VIP program. Although Organon was a small player and had only two products in the long-term care market, Remeron Tablet and Remeron SolTab, while other pharmaceutical companies, such as Pfizer or Bristol-Myers Squibb, had several products, Organon was ranked Vendor of the

Year in 2002 at PharMerica. Organon also achieved Diamond Level in 2002, meaning that it provided in excess of $150,000 for both Remeron Tablet and Remeron SolTab.

113. In addition to providing kickbacks in exchange for therapeutic interchange, Organon offered PharMerica nominally-priced Remeron in exchange for future business. While performing his normal job duties, Relator Banigan discovered that in the third quarter of 2001, Organon offered PharMerica a large amount of Remeron SolTab at a nominal price in order to dispose of Remeron SolTab that would expire quickly in exchange for the purchase of the same amount of Remeron SolTab at regular contracted prices.

ii. Omnicare

114. In February 1999, Organon contracted with Managed Healthcare Associates ("MHA"), a GPO, of which Omnicare was a member. Organon's February 17, 1999 contract with MHA pledged **ramp-up discounts of 14.8, followed by 8% to 15% discounts based on market tier in the post ramp-up period.** Even in 1999, such discounts were offered only to the GPO's long-term care members like Omnicare. Omnicare also received the advantage of a similar contract between Organon and GeriMed, another GPO of which Omnicare was a member.

115. On January 24, 2001, just as Remeron SolTab **was launched, MHA** and **Organon signed a new agreement,** which instituted new promotion requirements, **"conversion rebates"** and **"therapeutic interchange bonuses"** applying only to the new Remeron product. The 2001 contract boasted a 12% ramp-up rebate for Remeron SolTab and market share rebates ranging from 5% to 12%.

116. In February 2002, Organon contracted directly with Omnicare. This contract extended and increased Omnicare's ramp-up rebate to 14% until September 30, 2002, followed by a 4% to 16% market-share rebate. Organon amended the contract in July 2002 to add a conversion rebate of up to 3% based on conversion of Remeron Tablet prescriptions to Remeron SolTab. Although Omnicare did not grant Remeron SolTab "preferred" status or implement a therapeutic interchange, Omnicare did agree to place Remeron on "unrestricted access", defined in the 2002 contract as being available on Omnicare's formulary without any restrictions, such as prior authorization, NDC Locks, or the like, and as not being targeted for therapeutic interchanges to competitors' products. Organon's plan was successful; by mid-2002, Omnicare had the highest rate of conversion for any long-term care pharmacy provider.

117. Through several contract amendments, Organon continued to offer the 14% ramp-up rebates, conversion rebates, therapeutic bonuses, and market-share rebates in various forms provided to Omnicare until December 31, 2005.

118. In addition to the significant market-share rebates and discounts and the conversion and therapeutic interchange rebates that Organon offered to Omnicare, Organon and Omnicare concocted various other schemes to funnel money to Omnicare for purchasing and recommending Remeron. For example, the Omnicare strategy in the Business Plan included budgeting for "grants to fund studies," sponsorship of annual meetings, ReView Initiative, AccuMed software, and Omnicare Senior Care Outcome Initiatives. Business Plan, Exhibit 2, p. 9.

119. Moreover, in November 2001, Relator Banigan became personally aware of Organon's offer to Omnicare of a substantial quantity of Remeron SolTab at nominal

prices in an effort to dispose of short-dated product. Organon specifically selected Omnicare because Omnicare had not yet converted to Remeron SolTab. Organon achieved exactly what it wanted—Omnicare's conversion was kick-started. Business Plan, Exhibit 2, p. 8.

120. Like PharMerica, Omnicare actively pursued Organon to participate in corporate partnership programs, which were mainly ways to funnel money to Omnicare in exchange for Remeron prescriptions.

iii. NeighborCare

121. Like Omnicare, NeighborCare was a member of both GeriMed and MHA GPOs and was privy to the pricing provided by Organon on Remeron under those contracts in 1999. In February 1999, Organon contracted with Managed Healthcare Associates ("MHA"), a GPO of which Omnicare was a member. Organon's February 17, 1999 contract with MHA pledged **ramp-up discounts of 14.8, followed by 8% to 15% discounts based on market tier in the post ramp-up period.** Organon had a similar contract with GeriMed.

122. Unlike Omnicare and PharMerica, NeighborCare decided to continue receiving its contract pricing through a GPO—Owen, later called Cardinal Health Provider Pharmacy Services. Organon and Owen Healthcare, Inc. ("Owen") entered into an agreement on March 1, 2001 that employed the same basic terms as GeriMed's and MHA's, and included a **12% ramp-up discount through September 30, 2001, followed by 5% to 12% discounts based on market tier in the post ramp-up period, plus a 1.5% therapeutic interchange bonus and a conversion rebate of up to 3%,** all available only to long-term care members. These market-tier discounts were derived at the

individual long-term care pharmacy provider level and were not based on consolidated performance by all GPO members. WAC prices increased, but discount and rebate percentages remained the same in a June 2001 amendment.

123. By 2002, NeighborCare was the only long-term care pharmacy provider member in the Owen GPO, as Omnicare had acquired American Pharmaceutical Services. With a new agreement becoming effective on March 1, 2002, **the ramp-up discount increased to 14%, while the market tier rebates ranged from 4% to 16%.** A **9.5% rebate was offered only on Remeron Tablet until April 30, 2002**, but no conversion rebate was offered. A March 2002 amendment to that agreement reflects that the parties had negotiated the **addition of a conversion rebate** to Exhibit B after Owen began shifting Remeron Tablet prescriptions to Remeron SolTab scripts. **Several amendments through 2003 extended the 14% ramp-up discount**, but reduced the market share tiers downward.

124. Organon also offered other incentives to NeighborCare to entice it to convert Remeron Tablet prescriptions to Remeron SolTab and to implement a therapeutic interchange program that would grant Remeron "preferred" status. For example, the Business Plan recommended budgeting for the following NeighborCare initiatives: data purchasing, educational mailings, provision of educational and clinical services, personalized introduction for an in-service program on depression, $25,000 to sponsor annual meetings, conversion letters, conference calls, newsletters, and participation in advisory boards. NeighborCare also solicited kickbacks for conversion and therapeutic interchange in the guise of corporate partnership initiatives.

iv. NCS Healthcare

125. Like NeighborCare, NCS Healthcare was a member of both GeriMed and MHA GPOs. NCS Healthcare benefited from the pricing provided by Organon on Remeron under those contracts in 1999. In February 1999, Organon contracted with Managed Healthcare Associates ("MHA"), a GPO, of which Omnicare was a member. Organon's February 17, 1999 contract with MHA pledged **ramp-up discounts of 14.8, followed by 8% to 15% discounts based on market tier in the post ramp-up period**. Organon had a similar contract with GeriMed.

126. NCS Healthcare refused to contract directly with Organon, instead it became a member of Committed Provider Services, a GPO. In January 2001, Organon contracted with Committed Provider Services, providing for a **12% ramp-up discount through September 30, 2001 and a 5% to 12% chargeback discount** after that based on market tier. The contract also included a **1.5% therapeutic interchange bonus and a conversion rebate of up to 3%** for prescriptions converted from Remeron Tablet to Remeron SolTab available only to long-term care members of Committed Provider Services. Organon terminated the contract on April 20, 2002. Upon information and belief, Organon continued to allow NCS Healthcare to access this contract pricing until Omnicare acquired NCS Healthcare in 2003.

127. Organon offered kickbacks to NCS Healthcare for conversion and implementing a therapeutic interchange program in which Remeron was given "preferred" status. For example, the strategy for NCS Healthcare in the Business Plan budgeted $7,000 for conversion letters. Business Plan, Exhibit 2, p. 13. In addition, Maddox and McKenna set aside $10,000 to $20,000 to support the annual meeting for NCS Healthcare. Business

Plan, Exhibit 2, p. 13. Other means of funneling money to NCS Healthcare included data purchasing agreements and money for creation of newsletters.

v. American Pharmaceutical Services ("APS")

128. APS was one of the smaller of the large long-term care pharmacy providers. In February 1999, Organon contracted with Managed Healthcare Associates ("MHA"), a GPO, of which APS was a member. Organon's February 17, 1999 contract with MHA pledged **ramp-up discounts of 14.8, followed by 8% to 15% discounts based on market tier in the post ramp-up period**. Organon had a similar contract with GeriMed. APS refused to contact directly with Organon and instead chose to receive its contract pricing through GPOs, Owen (later called Cardinal Health Provider Pharmacy Services). Organon and Owen Healthcare, Inc. ("Owen") entered into an agreement on March 1, 2001 that employed the same basic terms as GeriMed's and MHA's, and included a **12% ramp-up discount through September 30, 2001, followed by 5% to 12% discounts based on market tier in the post ramp-up period, plus a 1.5% therapeutic interchange bonus and a conversion rebate of up to 3%**, all available only to long-term care members.

129. These market-tier discounts were derived at the individual long-term care pharmacy provider level and were not based on consolidated performance by all GPO members. WAC prices increased, but discount and rebate percentages remained the same in a June 2001 amendment.

130. With a new agreement becoming effective on March 1, 2002, **the ramp-up discount increased to 14%, while the market tier rebates ranged from 4% to 16%. A 9.5% rebate was offered only on Remeron Tablet until April 30, 2002**, but no

conversion rebate was offered. A March 2002 amendment to that agreement reflects that the parties had negotiated the **addition of a conversion rebate** to Exhibit B after Owen began shifting Remeron Tablet prescriptions to Remeron SolTab scripts. APS received this pricing until it was acquired by Omnicare in 2002.

vi. Sunscript

131. Sunscript was also another smaller chain of long-term pharmacies. Like APS, Sunscript refused to contact directly with Organon and instead chose to receive its contract pricing through MHA. Organon and MHA entered into an agreement on March 1, 2001 that included a **12% ramp-up discount through September 30, 2001, followed by 5% to 12% discounts based on market tier in the post ramp-up period, plus a 1.5% therapeutic interchange bonus and a conversion rebate of up to 3%**, all available only to long-term care members.

132. In an effort to entice Sunscript to establish therapeutic interchange programs and to engage in conversion of Remeron Tablet prescriptions to Remeron SolTab, Organon offered kickbacks in various forms, including but not limited to data sharing agreements and annual meeting sponsorships, to Sunscript. For example, the Business Plan proposed setting aside $15,000 per quarter for 2002 to purchase data from Sunscript and $15,000 to sponsor Sunscript's annual meeting. Business Plan, Exhibit 2, p. 14. Organon's plan worked; Sunscript placed Remeron on its "preferred" product list.

E. Long-Term Care Pharmacy Providers Paid Bonuses to Pharmacy Managers Based on Medicaid Profit

133. McKenna disclosed to Relator Banigan in a conversation that took place after November 25, 2003 that he had handled the PharMerica account. During the Remeron Medicaid scheme, according to McKenna, compensation to PharMerica general

managers and clinical directors was based in part on Remeron profit. Specifically, bonuses for both general managers and regional clinical directors were based upon weighted attainment of product initiatives. There were 22 products that qualified for this bonus, each of which was weighted and rated according to priority. Remeron Tablet had a priority rating of 7 out of 10, with 10 being the highest; Remeron SolTab had a rating of 9, which was based upon relative margin and opportunity to profit. PharMerica's initiative for Remeron Tablet was to shift the business away from other non-priority anti-depressants. When Remeron SolTab entered the market, discounts and rebates on Remeron Tablet were dropped to drive conversion to the new drug. Once this occurred, PharMerica eliminated Remeron Tablet' relative rating altogether and replaced the product on its list of initiatives with Remeron SolTab, which took the third slot in priority. Some of these discounts were passed onto the long-term care institutions, while a portion was retained by PharMerica and paid out as incentives to their site managers and clinical pharmacologists.

X. ORGANON OFFERED KICKBACKS TO RETAIL PHARMACY CHAINS, MAIL-ORDER PHARMACIES, AND MANAGED CARE PHARMACIES TO DRIVE CONVERSION TO REMERON SOLTAB

134. Organon also offered kickbacks to retail, mail-order and managed care pharmacies for the sole purpose of encouraging conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, rather than engaging in therapeutic interchange programs. These kickbacks took various forms, such as marketing the "spread" on Remeron SolTab versus the "spread" on Remeron Tablet at Medicaid's expense and other financial inducements.

135. In a memorandum, Rich Greene and Craig Franco directed Organon's Remeron sales force to "explain to them [retail pharmacies] that the spread between the

AWP and WAC of Remeron® SolTab™ is 20% versus 16 2/3% for the tablets" and that this spread would allow the pharmacies to increase their profits "by $1.20 to $1.80 per script."

XI. ORGANON DECREASED ITS OBLIGATIONS UNDER ITS REBATE AGREEMENTS WITH STATE MEDICAID PROGRAMS AND FAILED TO REPORT THE TRUE BEST PRICE

136. Under 42 U.S.C. § 1396r-8, in order for a manufacturer of a drug to have its products compensated under Medicaid, the manufacturer must enter into a rebate agreement with the Secretary of HHS. In Medicaid's multi-layered statutory system, even after Medicaid reimburses a pharmacy or provider for a prescription drug, it expects a quarterly accounting from the drug's manufacturer to ensure that it has received the "best price" for the drug industry-wide, and that the manufacturer pays a rebate for any shortfall. Organon decreased its rebate obligations with respect to Remeron Tablet and Remeron SolTab in three ways: 1) including the deep discounts and rebates that it illegally offered its long-term care pharmacy provider customers in its reported average manufacturer prices for Remeron Tablet and Remeron SolTab; 2) mischaracterizing transactions to avoid reporting its true best price for Remeron Tablet and Remeron SolTab; and 3) failing to maintain adequate procedures and control of its membership list of 340B covered entities to whom Organon must offer 340B pricing on all its drugs, including Remeron and Remeron SolTab.

A. Meaning of "Average Manufacturer Price" and "Best Price"

137. Organon entered into a rebate agreement with Medicaid, under which Organon had to comply with the rebate requirements set forth in 42 U.S.C. § 1396r-8, including reporting its "average manufacturer price" ("AMP") and "best price" for each of

its drugs to Centers for Medicare and Medicaid Services ("CMS") each quarter. AMP and best price are used to calculate the quarterly rebate payment that each participating manufacturer must make to state Medicaid pharmacy programs. The AMP is defined as "the average price paid to the manufacturer for the drug in the United States by wholesalers for drugs distributed to the retail pharmacy class of trade, after deducting customary prompt pay discounts." 42 U.S.C. § 1396r-8(k)(1). Discounts and rebates provided to long-term care pharmacy providers were a customary deduction from AMP during the relevant time period.

138. The Medicaid statute defines "best price" as "the lowest price available from the manufacturer during the rebate period to any wholesaler, retailer, provider, health maintenance organization, nonprofit entity or governmental entity." 42 U.S.C. § 1396r-8(c)(1)(C). The section also provides that "best price" includes "cash discounts, free goods that are contingent on any purchase requirement, volume discounts and rebates."

139. Best price does not include "prices that are merely nominal in amount" unless those nominal priced sales are contingent upon any purchase requirement. 42 U.S.C. § 1396r-8(c)(1)(C)(ii).

140. In addition, prices offered to 340B covered entities are not included in the best price calculation. 42 U.S.C. § 139r-8(c)(1)(C)(i). To assure that prices offered to 340B covered entities are not included in the rebate calculation, the Office of Pharmacy Affairs ("OPA") for Department of Health and Human Services maintains a "Medicaid Exclusion" file, which lists the current eligible 340B entities that have reported their intent to fill Medicaid prescriptions with 340B-purchased drugs. The "Medicaid Exclusion" file allows state Medicaid agencies to determine which 340B entities' claims must be excluded

for rebate requests from a drug manufacturer. Drug manufacturers also maintain 340B membership lists that track entities eligible to receive 340B pricing; these lists are generally updated on a quarterly basis.

B. Organon Decreased its Obligations under its Rebate Agreements with State Medicaid Programs

141. Organon's scheme to have its sales representatives fraudulently market the "Opportunity to Profit" from Remeron and Remeron SolTab ultimately impacted Organon's reported quarterly AMP calculations. Under Organon's rebate agreement with Medicaid, Organon was required to calculate its AMP by averaging its actual prices for Remeron Tablet and Remeron SolTab. In reviewing documents as part of his normal course of employment, Relator Banigan discovered that Organon made sure to deduct the deep discounts and rebates that it illegally offered to long-term care pharmacy providers on these drugs in making its AMP calculations. Doing so produced a lower AMP than if the discounts and rebates had not been considered. Under the formula used to calculate a pharmaceutical manufacturer's rebate liability, a reduced AMP results in a lower rebate amount due Medicaid. Organon therefore decreased its liability under its rebate agreement with Medicaid by including illegally-discounted long-term care discounts and rebates into its calculation of AMP.

142. In addition, Organon concealed its true "best price" from the Government. In order to enable Organon to circumvent setting a best price, Organon offered kickbacks in various forms to long-term care pharmacy providers, such as Omnicare, PharMerica, NeighborCare, NCS Healthcare, APS, and Sunscript. These kickbacks included, but were not limited to, data sharing agreements for the purchase of LTCPP prescribing data, research grants, educational grants, access fees, sponsorship of long-term care pharmacy

providers' annual meetings, advisory panels, and other forms of remuneration. By failing to disclose to Medicaid the payments it provided to long-term pharmacy providers, Organon misrepresented its true "best price" to Medicaid, thereby lowering its rebate liability to Medicaid.

C. Organon Avoided Reporting the True Best Price By Mischaracterizing Transactions as Nominal or Entering Into Improper Discount Arrangements

143. Organon avoided reporting its true best price for Remeron Tablet and Remeron SolTab by mischaracterizing transactions as nominal or through entering into improper discount arrangements.

144. For example, in at least two instances, one involving Omnicare and one involving PharMerica, Organon avoided disclosing the true best price by coupling the sale of nominally-priced Remeron SolTab that was about to expire with the requirement to purchase a similar quantity of Remeron SolTab at normal commercial prices. In November 2001, Relator Banigan became personally aware of Organon's offer to Omnicare of a substantial quantity of Remeron SolTab at nominal prices in an effort to dispose of short-dated product (i.e., product that would expire quickly). Organon selected Omnicare because Omnicare had not yet converted to Remeron SolTab. Both parties verbally understood that this offer was contingent upon Omnicare's later purchase of a similar quantity of Remeron SolTab at contracted discounts of 17%. Organon willfully violated best price requirements by disclosing the transactions independent of one another despite that fact that the nominal price offer was contingent upon a commercial sale. Had the two transactions been considered together, the best price calculation for the fourth quarter of 2001 would have dramatically dropped by an estimated 40%.

145. In reviewing documents as part of his normal course of employment, Relator Banigan discovered that Organon made a similar deal with PharMerica in the third quarter of 2001. Organon offered PharMerica a large amount of Remeron SolTab at a nominal price in order to dispose of Remeron SolTab that would expire quickly. This sale was conditional; PharMerica had to purchase a similar quantity of the drug at commercial prices. Organon structured the sale in a manner intended to defraud the government. In order to avoid disclosing the transaction, Organon sold the product to PharMerica through a wholesaler rather than by a direct sale to PharMerica. The result, however, is the same: Organon failed to report the true best price by disclosing the transactions independent of one another even though best price requirements required Organon to report them together.

146. Shortly after the PharMerica transaction occurred, Banigan requested a meeting with Organon's president, Michael Novinski, to discuss his concerns about the transaction. Novinski acknowledged that he was aware of the PharMerica transaction and that he was "happy" about it. When Banigan expressed his concerns about the implications of the transaction on best price calculations, Novinski asked how much it would cost to fix the problem and the chances of getting caught. Banigan explained that the problem would probably cost around $1 or $2 million to correct and that the chances of getting caught were low. Novinski responded that Banigan should leave the issue alone. Worried that he would be terminated, Banigan did not pursue the issue further.

147. Organon also lowered its rebate liability by participating in an improper discount arrangement with Kaiser Permanente ("Kaiser"). In 1997, Organon entered into a fixed-price contract with Kaiser to provide several of its products, including Remeron, at discounted prices. On June 20, 1999, Organon and Kaiser amended the contract to extend

the discounts for another three years. On February 28, 2001, Organon raised the price of Remeron. Realizing that Kaiser's discounted Remeron price would result in a new best price, Organon approached Kaiser to resolve the issue. The contract, however, failed to provide for cancellation or price adjustments should the product prices increase. Kaiser told Organon that it could either buy itself out of the contract or provide the same discounts to which Kaiser was entitled on Remeron under contract on another drug product that was not setting a best price. Organon agreed to discount Zemuron, a muscle stimulant with little or no Medicaid sales used mainly in hospitals, in exchange for increasing the price of Remeron. In order to conceal the best price violation, Organon backdated the amendment to the Kaiser contract to make the prices effective as of April 1, 2001 and backed out any transactions for Remeron that had occurred since April 2001 in its chargeback system. Pursuant to this understanding, Organon and Kaiser continued to amend the original fixed-price contract as the price of Remeron increased until at least 2004. This new arrangement allowed Organon to hide the discounts and avoid reporting its true best price on Remeron, thereby reducing its rebate liability to state Medicaid programs.

148. In addition, Organon's failure to report the true best price caused other federal purchasers, such as entities qualifying for 340B pricing, the Department of Defense, the Veterans' Administration, the Bureau of Prisons, and the Bureau of Indian Affairs, to pay higher prices for Remeron Tablet and Remeron SolTab, because the federal government uses best price reporting to set prices for 340B entities and the Federal Supply schedule.

D. Organon Sold Remeron at 340B Pricing to Ineligible Entities, Causing Its Best Price Reporting to Be Inaccurate for Some Quarters

149. Organon fraudulently violated its Medicaid rebate agreement in a further respect, by failing to maintain adequate procedures and control of its membership list of 340B covered entities to whom Organon must offer 340B pricing on all its drugs, including Remeron and Remeron SolTab. 340B sales transactions are exempt from best price determination, to the extent that these government prices are only extended to 340B eligible entities. Organon was advised of these issues but elected not resolve the matter. Organon understood that not including such transactions in its reported "best price" calculation would grossly lower their Medicaid rebate liability.

150. In addition, Organon intentionally or recklessly failed to maintain its membership list of 340B covered entities. Organon was permitted under the Public Health Service Act of 1992 to sell its drugs to 340B covered entities under special government pricing. See 42 U.S.C. § 256b. Organon's failure to maintain its membership list of 340B-covered entities caused Organon to sell its drugs, including Remeron Tablet and Remeron SolTab, at the special 340B pricing to customers who were not qualified to receive this pricing. While transactions involving the sale of Remeron and Remeron SolTab at 340B pricing to eligible 340B entities are exempt from best price calculations, sales to entities that are or have become ineligible are not. If transactions involving the sale of Remeron Tablet and Remeron SolTab at the special government pricing provided to ineligible entities had been included in Organon's best price calculation, a new best price would have been set for at least some of the previously reported calendar quarters.

151. Banigan learned of this issue in 1999 or 2000 during a routine check of the government pricing systems to validate government pricing calculations. As part of the check, Banigan randomly audited a sampling of the master customer list to determine

whether customers were listed under the correct class of trade, e.g. "entity eligible to receive government pricing." Banigan analyzed a few of the customers listed as entities that received government pricing and determined that these customers were ineligible under Section 340B to receive this pricing.

152. Realizing that Organon was not maintaining its membership list of 340B covered entities and concerned about Organon's exposure due to this failure, Banigan spoke with Sean Gallagher, the Associate Director of Contracting Department for Organon, as the Contracting Department was responsible for maintaining the membership list. Gallagher explained to Banigan that Organon did not routinely check the list published by OPA to determine an entity's eligibility to receive government pricing under Section 340B. Instead, Organon would sometimes place an entity on the membership list, if that entity identified itself as being an eligible 340B entity. Gallagher reluctantly agreed to have his staff perform a review of the 340B membership list and correct the problem. Organon, however, did not attempt to recover the commercial price from the ineligible entities, nor did it restate its best price to the government under its Medicaid rebate agreement.

153. Despite assurances that the problem had been corrected, Banigan encountered the same issue again when, every year or so, he performed routine checks of the government pricing system to validate government pricing calculations. Each time, Banigan would report the problem to the Contracting Department and to senior management, the Contracting Department would assure Banigan that the problem had been resolved. Banigan did not see any changes in the maintenance procedures of the 340B covered entity membership list, until 2005, when the management of the Contracting Department changed. At that time, a written policy or work instruction was established,

requiring that Organon personnel verify a customer's 340B eligibility through the OPA website before placing that entity on the Organon 340B covered entity membership list. Once an entity's 340B eligibility was verified, it was listed as a member able to receive a 340B contract price; the continuing eligibility of that entity was never re-validated. Thus, following implementation of procedures in 2005, Organon still would have sold products at 340B pricing to ineligible entities, causing false best prices to be set in certain quarters.

154. Banigan discussed Organon's failure to maintain its 340B covered entity membership list and the effect on best price reporting several times with Organon's senior management. When Banigan suggested that Organon restate its best price and rebate liability under its Medicaid agreement, senior management told him that Organon would not go back, but would correct the problem going forward. In fact, senior management would not authorize resources to audit the government pricing system to correct problems with the system, including the problems with Organon's membership list of 340B covered entities.

155. As a result of Organon's failure to maintain its membership list of 340B covered entities, Organon sold Remeron Tablet and Remeron SolTab at 340B pricing to entities ineligible to receive this special pricing. Any transactions with these ineligible entities would have been considered commercial transactions and therefore should have been included when calculating best price. Yet Organon failed to report transactions involving these ineligible entities and excluded them from the best price reporting, claiming that these transactions involved 340B eligible entities. Furthermore, Organon made no attempt to extract from these ineligible entities the unintended discount. Instead,

Organon would remove the ineligible entity from the membership list and simply move forward as if nothing ever happened.

156. It is estimated that twenty percent of the quarterly best price filings for Organon's drugs, including Remeron and Remeron SolTab, were rendered false due to the inclusion of ineligible entities in the 340B covered entities membership list. As a result, Organon's liability under its Medicaid rebate agreement was thus reduced in some quarters from 1999 to 2006, resulting in significant damages. In addition, Organon's failure to report a true best price in some quarters from 1999 to 2006 caused other federal purchasers, such as 340B entities, the Department of Defense, the Veterans' Administration, the Bureau of Prisons, and the Bureau of Indian Affairs, to pay higher prices for Remeron Tablet and Remeron SolTab, because the federal government uses best price reporting to set prices for 340B entities and the Federal Supply schedule.

XII. ORGANON'S OFF-LABEL MARKETING OF REMERON

A. Statutory and Regulatory Background

i. The FDA's Role in the Regulation of Prescription Drugs

a. FDA Approval of Prescription Drugs

157. The FDA regulates human use of pharmaceutical drugs such as Remeron and Remeron SolTab. Companies seeking to introduce new drugs for human use into interstate commerce must comply with FDA statutes and regulations, such as the Federal Food, Drug and Cosmetic Act ("FDCA"). 21 U.S.C. § 301, *et seq*. Notably, the FDCA prohibits companies from distributing in interstate commerce any drugs that the FDA has not approved as safe and effective. 21 U.S.C. § 355(a) and (b).

158. In order for a company to gain approval of a drug by the FDA, the

company must first submit and receive approval of a New Drug Application ("NDA") pursuant to 21 U.S.C. § 355. The company is required to include in its NDA all intended uses proposed for a new drug's labeling and to prove that the new drug is safe and effective for those uses. 21 U.S.C. § 355(b). To prove that the drug is safe and effective, the company must provide the FDA with data from scientifically sound clinical trials. The FDA will refuse approval of a new drug unless, on the basis of all information reviewed, it is demonstrated that a drug can safely accomplish its purported effect under the conditions proposed, and that the method of manufacture and distribution will properly preserve the drug for this purpose. 21 U.S.C. § 355(d).

b. FDA Regulation of Manufacturers' Marketing of Prescription Drugs

159. When the FDA reviews an NDA and approves a drug for interstate distribution, that approval is only effective for the intended uses that were proposed in the NDA and described on the drug's approved label. Any use for a drug that was not proposed in the NDA and approved for the label by the FDA is referred to as "unapproved" or "off-label." 65 Fed.Reg. 14286, 14286 (Mar. 16, 2000). Although physicians traditionally may prescribe a drug for an off-label use so long as the drug has been FDA-approved for some use, pharmaceutical companies are strictly prohibited from marketing a drug for an off-label use.

160. When a company markets a drug off-label, the drug becomes a new drug for that purpose and is considered "misbranded" in violation of 21 U.S.C. § 331; 21 U.S.C. § 352(f); 21 C.F.R. § 310.3 (h)(4) and (5); 65 Fed.Reg. 14286, 14286 (Mar. 16, 2000) ("an approved new drug that is marketed for a 'new use' is also 'misbranded' under the FDCA, because the labeling of such a drug would not include 'adequate directions for use'").

Section 352 of title 21 of the United States Code lists situations in which a drug is illegally misbranded, including but not limited to situations where: (1) the drug's labeling is "false or misleading in any particular;" (2) the drug's labeling does not bear adequate direction for use; or (3) the drug's labeling does not bear "adequate warnings against use in those pathological conditions or by children where its use may be dangerous to health, or against unsafe dosage or methods or duration of administration or application, in such manner and form, as are necessary for the protection of users . . . ." *See* 21 U.S.C. § 352(a) and (f).

161. The term "labeling" encompasses the actual label attached to the drug's immediate container, as well as all "other written, printed, or graphic matter (1) upon any article or any of its containers or wrappers, or (2) accompanying such article." 21 C.F.R. § 321(m). The term has been construed to include a variety of drug company promotional materials, including booklets, pamphlets, and literature that is textually related to the product, even when disseminated without the presence of the drug. *See Kordel v. United States*, 335 U.S. 345, 349 (1948); *V.E. Irons, Inc. v. United States*, 244 F.2d 34, 39 (1st Cir. 1957). In determining if a drug's labeling or advertising is misleading and thus misbranded, one must examine "(among other things) not only representations made or suggested by statement, word, design, device, or any combination thereof, but also the extent to which the labeling or advertising fails to reveal facts material in the light of such representations or material with respect to consequences which may result from the use of the article" as described by the labeling or advertising or the customary or usual use of the article. 21 U.S.C. § 321(n).

162. In order for a drug's labeling to include "adequate directions for use," the directions must allow a layman to use the drug safely and for its "intended use." *See* 21

C.F.R. § 201.5. The "intended use" of a drug refers to "the objective intent of the person legally responsible for the labeling of drugs." *See* 21 C.F.R. § 201.128. "The intent is determined by such persons' expressions or may be shown by the circumstances surrounding the distribution of the article," and "may, for example, be shown by labeling claims, advertising matter, or oral or written statements by such persons or their representatives." *Id.* Thus, if a manufacturer promotes a drug for a use for which the label does not provide adequate directions for use or is otherwise false and misleading, misbranding has occurred, regardless of Medicaid or Medicare Part D's reimbursement of the drug for this use.

163. Over the years, the FDA has issued regulatory guidances to aid manufacturers in distinguishing between these illegal marketing strategies and legitimate non-promotional dissemination of information on off-label uses, by setting forth factors to determine whether a manufacturer's dissemination of information is actually promotional. These guidances make it clear that pharmaceutical manufacturers cannot use reprints, reference texts or Continuing Medical Education ("CME") programs as tools to promote off-label uses. *See* Guidance to Industry on Dissemination of Reprints of Certain Published, Original Data, 61 Fed.Reg. 52800 (Oct. 8, 1996); Guidance for Industry Funded Dissemination of Reference Texts, 61 Fed.Reg. 52800 (Oct. 8, 1996); Final Guidance on Industry-Supported Scientific and Educational Activities, 62 Fed.Reg. 64074 (Dec. 3, 1997); Guidance for the Industry: Good Reprint Practices for the Distribution of Medical Journal Articles and Medical or Scientific Reference Publications on Unapproved New Uses of Approved Drugs and Approved or Cleared Medical Devices, 74 Fed.Reg. 1694-01

(Jan. 13, 2009). None of these guidances has changed the FDA's long-standing prohibition against marketing and promoting of approved drugs for off-label uses.

ii. Reimbursement of Off-Label Prescription Drugs under Medicaid

164. In addition to meeting the FDA drug approval requirements, Organon applied for and received Medicaid coverage for Remeron and Remeron SolTab in each of the fifty states, including the States of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, and Texas, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago. As a general rule, to be reimbursable under a state's Medicaid program, a drug must be included on the state's formulary. Each state has its own means of deciding coverage, but federal law sets forth requirements states must meet in excluding or restricting coverage. *See* 42 U.S.C. § 1396r-8. A state may exclude or restrict coverage of a drug in four instances:

(1) the prescribed use is not for a medically accepted indication;
(2) the drug is on a list of drugs excluded by the state from Medicaid coverage;
(3) the drug manufacturer agreed to the restrictions on the drug in its rebate agreement with Medicaid; or
(4) the drug was excluded from the state's drug formulary.

31 U.S.C. § 1396r-8(d)(1). In addition, states may use prior authorization programs or preferred drug lists to control potential abuses of drugs, such as prescriptions for an indication that is not a medically accepted indication.

165. A "medically accepted indication" is a use that is listed in the labeling approved by the FDA or "the use of which is supported by one or more citations included

or approved for inclusion in" one of the drug compendia identified by the Medicaid statute. 42 U.S.C. § 1396r-8(k)(6). These compendia are the American Hospital Formulary Service Drug Information, the United States Pharmacopeia-Drug Information (or its successor publications), and the DRUGDEX Information System. 42 U.S.C. § 1396r-8(g)(b)(i). The United States Government and the states interpret "supported by" to require "some form of corroboration or validation." *See* Centers for Medicare and Medicaid Release No. 141 (May 4, 2006) ("The statute requires coverage of off-label uses of FDA-approved drugs for indications that are supported (as opposed to listed) in the compendia specified in section 1927(g)(1)(B)(II)").

166. States may establish drug formularies if they meet the following requirements. *See* 42 U.S.C. § 1396r-8(d)(4). The formulary must be developed by a committee consisting of pharmacists, physicians and other qualified individuals appointed by the governor or by the state's Drug Use Review ("DUR") board consisting of healthcare professionals who have recognized knowledge and expertise in the prescription, dispensing and monitoring of outpatient drugs, drug use review, and medical quality assurance. 42 U.S.C. § 1396r-8(d)(4)(A) and § 1396r-8(g)(3).

167. The formulary must include every drug for which a manufacturer has entered into a Medicaid rebate agreement. 42 U.S.C. § 1396r-8(d)(4)(B). The state may, however, exclude a drug from the formulary if: (1) the drug is used for an on-label use -- or an off-label use that is a medically accepted indication based on compendia -- but the drug does not have a significant, clinically meaningful therapeutic advantage over other drugs on the formulary; and (2) the state provides a written explanation, which is available to the public, of why the drug is excluded. 42 U.S.C. § 1396r-8(d)(4)(C). Finally, any

drugs excluded from the formulary must nevertheless be available to Medicaid enrollees under a prior authorization program. 42 U.S.C. § 1396r-8(d)(4)(D).

168. States generally have some method for drug manufacturers to request that its drug be added to the states' "preferred drug lists." In the majority of states, the Pharmaceutical and Therapeutics committee or the DUR board makes the decision on whether to add drugs to the state Medicaid program's preferred drug list. Generally, these committees announce that they will conduct a review of a class of drugs. At that time, a drug manufacturer may submit information to the committees to be considered for the drug list. A minority of states, such as Indiana, Montana, Nevada and Texas, require drug manufacturers to submit an application to be placed on the drug list. As part of the Texas application, drug manufacturers are required to expressly certify compliance with all laws, regulations and rules applicable to the Medicaid program, including the federal and state Anti-Kickback statutes.

169. Pharmaceutical Therapeutics Committees and DUR boards are required to continually "assess data on drug use against predetermined standards," using the compendia as the source for these standards. 42 U.S.C. § 1396r-8(g)() and (2). These standards include but are not limited to monitoring for therapeutic appropriateness, overutilization and underutilization, appropriate use of generic products, drug-drug interactions. *Id.* The States' continual assessment of drug data permits them the flexibility to determine the appropriate scope, duration, and limitations on coverage of drugs on their formularies.

B. Organon's Off-Label Marketing Scheme

170. As described below, Organon engaged in a nationwide off-label marketing scheme that not only violated the FDA prohibitions against marketing off-label uses of drugs and illegally misbranding drugs, but also violated the Anti-Kickback statute. Further, upon information and belief, Organon purposefully manipulated drug compendia, such as DRUGDEX, and caused them in some cases to list desired off-label uses. For example, the 2008 edition of DRUGDEX lists two studies on the use of mirtazapine (Remeron and Remeron SolTab) in treating adults with depression for anxiety. The studies state that the drug and financial support for the study were provided by Organon. In addition to uses listed in the drug compendia, Organon also promoted other off-label uses that do not appear in any of the drug compendia, such as insomnia, weight gain and anxiety. As a result of this nationwide scheme, Organon reaped profits beyond those it would have achieved from legitimate promotion.

i. FDA Approval of Remeron and Remeron SolTab

171. The FDA approved Remeron tablets on June 14, 1996 and Remeron SolTab on January 12, 2001. Both drugs are indicated for the treatment of depression, specifically for major depressive episodes. Neither drug has been approved for use in children and adolescents. The Diagnostic and Statistical Manual for Mental Disorders 4th edition ("DSM-IV") defines a major depressive episode as a prominent and relatively persistent depressed mood that interferes with daily functioning along at least five of the following nine symptoms: 1) depressed mood, 2) loss of intent in usual activities, 3) significant change in weight and/or appetite, 4) insomnia (inability to sleep) or hypersomnia (excessive daytime sleepiness), 5) psychomotor agitation or retardation, 6)

increased fatigue, 7) feelings of guilt or worthlessness, 8) slowed thinking or impaired concentration, and/or 9) suicidal ideation or attempt.

172. The FDA-approved labeling for both drugs includes warnings and precautions. In particular, the labeling warns that use of Remeron and Remeron SolTab may result in somnolence (drowsiness), increased appetite or weight gain, and even anxiety. But instead of warning customers of the side effects of Remeron and Remeron SolTab, Organon initiated an off-label scheme aimed at marketing these side effects to customers. Furthermore, Organon made the off-label claim that Remeron and Remeron SolTab were effective treatments for patients with anxiety, despite a 1999 warning from the FDA that this claim was false and misleading.

173. The FDA-approved labeling for Remeron SolTab also noted that caution should be used in treating geriatric[2] patients with Remeron SolTab. Remeron SolTab is metabolized mainly by the kidney; thus, patients with impaired renal function are less likely to rid their bodies of the drug. The label warns that "Because elderly patients are more likely to have decreased renal function, care should be taken in dose selection." The labeling also advised that sedating drugs, like Remeron SolTab, may "cause confusion and over-sedation in the elderly." Despite these concerns, Organon created a plan to market Remeron and Remeron SolTab as the "ideal" antidepressant for elderly patients.

ii. Off-Label Marketing of Remeron and Remeron SolTab

174. Remeron never achieved "household name" status like Prozac, Paxil or Zoloft, as Organon had hoped. This was due in part to Remeron's two most common side effects, somnolence and weight gain, which were troublesome to most depression sufferers. Realizing that those side effects could be framed as "positive" for one patient profile—the

[2] The FDA defines "geriatric" as including patients 65 years of age and older. 21 C.F.R. § 201.57(f)(10).

elderly patient, Organon devised a scheme to market these attributes to healthcare providers, as though the side effects were approved indications. Organon positioned Remeron as the "ideal therapy for older depressed patients who experience anxiety and sleep disturbances." Organon refined this message for the long-term care sector and actually trumpeted Remeron's weight gain effect.

175. In addition to promoting Remeron as an anti-anxiety substitute and "playing up" Remeron's side effects of sedation and weight gain, Organon made the off-label claims that Remeron was a good choice among anti-depressants because of Remeron's minimal inhibition of the P450 enzyme and fast onset of action in relieving depression symptoms, such as sleep disturbances.

176. Organon also promoted the off-label use of Remeron in children and adolescents for the treatment of depression, attention deficit disorder ("ADD") and attention deficit hyperactivity disorder ("ADHD").

a. 1999 FDA Warning Letter

177. On January 5, 1999, Organon received a warning letter from DDMAC regarding various promotional materials for Remeron Tablet. *See* Letter from DDMAC to Organon (Jan. 5, 1999), *available at* http://www.fda.gov/CDER/warn/jan99/6950.pdf (last visited Sept. 10, 2008) (hereinafter "Warning Letter"). The Warning Letter advised that some of Organon's representations about Remeron were false and misleading, including but not limited to: 1) Remeron was effective in treating anxiety; 2) Remeron can relieve anxiety induced by selective serotonin reuptake inhibitors ("SSRIs"); 3) the implication that Remeron relieves anxiety symptoms as early as one week of use; 4) Remeron is safer or more effective than SSRIs; 5) Remeron has no significant inhibition of cytochrome P450

enzymes. The DDMAC recommended that Organon immediately cease distribution of materials bearing these messages.

(I) Anti-anxiety

178. The majority of the Warning Letter focused on Organon's representations regarding Remeron's ability to improve anxiety. The Warning Letter stated that the representation that Remeron was effective in treating anxiety was false and misleading because:

> Remeron may relieve depression-associated anxiety to the extent the anxiety is a symptom that is sometimes associated with depression. However, a claim that Remeron is effective in relieving anxiety and materials that focus on Remeron's ability to relieve anxiety are not substantiated.

See Warning Letter. As further evidence that Organon's anti-anxiety representation was false and misleading, the DDMAC pointed out that the FDA-approved product labeling for Remeron listed anxiety as a frequent adverse event, meaning that in some cases Remeron actually causes anxiety. The DDMAC also disapproved of Organon's representation that Remeron can relieve anxiety induced by SSRIs as lacking substantiation. The DDMAC further criticized Organon's claim that Remeron could improve symptoms of anxiety as early as the first week of use as false and misleading because it implied that Remeron worked within the first week to relieve depression, an unsubstantiated claim.

(II) Remeron Is More Effective than SSRIs

179. The DDMAC also condemned Organon's claims that Remeron was more effective than SSRIs as false and misleading. The DDMAC noted this representation implied superiority without substantiation from well-controlled comparative studies

(III) Remeron Lacks Significant Inhibition of Cytochrome P450 Enzymes

180. Finally, the DDMAC criticized Organon's claims that Remeron lacked significant inhibition of Cytochrome P450 enzymes. Cytochrome P450 enzymes are some of the major enzymes involved in the human body's metabolism of drugs. Some drugs inhibit Cytochrome P450 enzymes, causing the drug to accumulate in the bloodstream, potentially leading to heart arrhythmia, cardiac arrest, and even death.

181. Recognizing the importance of the Cytochrome P450 enzymes to physicians and pharmacists, Organon claimed that Remeron Tablet did not inhibit Cytochrome P450 enzymes. In the Warning Letter, the DDMAC found this representation to be false and misleading because no formal drug interaction studies had been conducted to substantiate this claim, and further, Remeron's own FDA-approved labeling stated that it is metabolized by some of the Cytochrome P450 enzymes. Due to these two factors, it was not possible to make a definitive statement about the risks associated with the coadministration of Remeron with other drugs metabolized by the Cytochrome P450 enzymes. The DDMAC thus asked Organon to cease in making this representation.

b. Organon's Continued Misrepresentations About Remeron

182. Even after the DDMAC recommended that Organon cease distribution of materials that stated or implied the violative messages, Organon continued to promote Remeron using these representations. Beginning as early as 2000, Organon positioned Remeron as the ideal drug for treating older patients with anxiety and sleep disturbances throughout the various customer sectors, including primary care and psychiatrists.

183. In addition, sometime after Remeron SolTab was launched in January 2001, Organon hired pharmacist Dana Saffel to design formal marketing materials, the Toolkit and its accompanying CD, to market these off-label uses of Remeron. The Toolkit was widely used by the Organon Long-Term Care sales force as the primary tool for selling to both long-term care clinicians and long-term care pharmacy consultants. Saffel's cover letter made clear that the Toolkit was designed to be used by long-term care pharmacy providers to persuade pharmacy providers to choose Remeron SolTab as its preferred anti-depressant and to teach these providers how to implement a therapeutic interchange program. Not only did the Toolkit contain Organon's false and misleading representations about Remeron's ability treat anxiety and its lack of inhibition of Cytochrome P450 enzymes, but the Toolkit contained Organon's new plan to market Remeron as a substitute for sedatives and appetite stimulants based on its side effect profile.

184. Section I of the Toolkit was devoted to Remeron's "therapeutic efficacy" and promoted Remeron's sedative, anti-anxiety and weight gain qualities to long-term care administrators. Section I, for example, repeated Organon's violative off-label message that Remeron was effective in treating anxiety. On page 2 of Section I, the Toolkit proclaimed that "[t]he side effect profile of mirtazapine [Remeron] can be quite attractive, especially in the elderly depressed patient with anxiety, agitation, insomnia, and weight loss." *See* Toolkit, Exhibit 1. Pages 47 and 48 in Section I of the Toolkit were devoted to using clinical studies to represent that Remeron was effective in reducing anxiety in patients within the first week of treatment. *See* Toolkit, Exhibit 1. Moreover, several pages in Section I discussed that Remeron could act as a substitute for anti-anxiety agents, reducing the need for adjunctive medications. *See* Toolkit, Exhibit 1. Section I of the Toolkit also

repeated Organon's violative message that Remeron had minimal inhibition of the Cytochrome P450 enzymes. *See* Toolkit, Exhibit 1, pp. 9, 82. The Toolkit stated: "Lack of clinically significant P450 inhibition and the relatively low protein binding make clinically significant interactions unlikely." *See id.* at p. 82.

185. In addition, in Section I of the Toolkit, Organon introduced its claim that Remeron could be used as a substitute for sedatives and hypnotics. Throughout the Toolkit, Remeron was praised as improving sleep disturbance. For this reason, Organon claimed, use of Remeron might eliminate the need for the use of a sedative or hypnotic drug as well. For example, on page 43 of Section I, the Toolkit stated: "Mirtazapine [Remeron] can treat insomnia without the use of 'inappropriate' sedative-hypnotics." The Toolkit then urged on page 53 of the same section that "Since up to 90% of patients with depression experience insomnia, using a drug that promotes sleep while also effectively treating depression can be a good therapeutic option." Later in Section I of the Toolkit, Remeron's side effect of somnolence was touted as the most frequently occurring adverse event for Remeron, implying that Remeron may be a substitute for sedatives. *See* Toolkit, Exhibit 1, p. 57.

186. The Toolkit also discussed Organon's claim that Remeron could be used as a substitute for appetite stimulants. Pages 44 and 45 of Section I focused on two studies that demonstrated that patients using mirtazapine experienced the adverse effect of weight gain. On page 46, the Toolkit stated: "Since 30 to 50% of NH residents have substandard body weight, using a drug that promotes appetite and weight gain while also effectively treating depression can be a good therapeutic option." Several pages later, the Toolkit exaggerated Remeron's side effect of weight gain, pointing out that 17% of patients gained

weight while using mirtazapine, implying Remeron's usefulness as an appetite stimulant substitute. *See* Toolkit, Exhibit 1, p. 57.

187. As discussed above, Section II, entitled "Contract Evaluation," of the Toolkit discussed pharmacy providers' opportunity to increase profits by encouraging the prescribing of Remeron. As part of this discussion, the Toolkit emphasized that in addition to taking advantage of the spread, pharmacy providers could increase profits by prescribing Remeron and eliminating the use of adjunctive drug prescriptions for sedatives, anti-anxiety agents, and appetite stimulants. The Toolkit suggested that a provider could save between $21to $215 per month per medication by switching to Remeron and discontinuing these drugs.

188. Finally, Section III of the Toolkit provided step-by-step directions for implementing a therapeutic interchange for Remeron. Section III included notification letters to physicians, facility administrators, directors of nursing and facility for pharmacy providers to use in explaining the reason the pharmacy provider chose Remeron as a preferred drug. In addition, Section III of the Toolkit contained sample recommendations that consultant pharmacists could use to persuade physicians to switch to Remeron SolTab. These notification letters and recommendations not only represented that Remeron SolTab improved anxiety, insomnia and appetite and caused weight gain and therefore could be a substitute for anti-anxiety agents, but that Remeron was more effective than SSRI antidepressants, a claim that, as discussed above, the FDA had already warned Organon was false and misleading. Incredibly, the notification letters also claimed that "SSRI antidepressants such as Zoloft, Prozac, Paxil, and Celexa should not be used when a depressed resident is suffering from insomnia because they can actually *cause* insomnia

and anxiety." *See* Toolkit, Exhibit 1, Section III (emphasis in original). This, of course, was the very point the FDA made to Organon as to why Organon's claims that Remeron was effective as an anti-anxiety agent were false and misleading.

c. Organon's Marketing Remeron for Treatment of Depression, ADD and ADHD in Children and Adolescents

189. Although Organon's off-label messages primarily focused on the mature patient, Organon also promoted Remeron for off-label uses in children. For example, an internal Organon marketing plan for the Central Nervous System sector suggests that Remeron's side effects of somnolence and weight gain may be viewed as beneficial in children. A study of physicians' thoughts regarding Organon sales representatives' sales calls prepared by an outside vendor shows that sales representatives discussed off-label uses of Remeron in children. For example, one physician noted that a representative "helped" by providing the physician with statistics and information regarding the use of Remeron for ADD and ADHD in children and adolescents. Another physician stated that the sales representative explained that Remeron helped children, such as those with ADD, calm down and sleep.

190. In sum, Organon engaged in a systematic and widespread marketing scheme to promote several off-label usages of Remeron, at Medicaid's expense. Organon's off-label campaign likely injured patients by leading doctors to prescribe drugs that were medically ineffective and substantially inappropriate. In many cases in which Remeron was prescribed for off-label attributes, it was prescribed in conjunction with another anti-depressant. Remeron's frequent use as "adjunctive therapy" further burdened Medicaid, which was paying for its patients to receive two anti-depressants at the same time. It is not

known what physical harm may have been imposed upon elderly patients whose ability to eliminate these and other medications was greatly compromised.

C. Organon's Use of Kickbacks

191. In the long term care sector, the "opportunity to profit" from prescriptions was the prime selling point for Remeron customers, who were mostly LTCPPs rather than physicians. In that sector, Organon used its off-label messages, particularly weight gain, anti-anxiety and somnolence, simply to aid the LTCPPs in justifying to physicians and others facilitating a therapeutic interchange from a competitor antidepressant to Remeron SolTab or from Remeron Tablet to Remeron SolTab.

192. In primary care and other sectors, in contrast, prescribing physicians with no parallel "opportunity to profit" were the targets of Organon's marketing. Within these sectors, Organon used kickbacks to influence physicians in at least two ways. First, in order to disseminate the off-label information described above, Organon needed effective messengers beyond just sales representatives; it needed a small number of high-profile experts in related fields to extol Remeron's virtues to other physicians. Without substantial speaker fees, advisor's fees, grants, and other perks, Remeron simply would not have been able to recruit such "thought and opinion leaders" on the strength of the drug alone.

193. At least as important to increasing Remeron sales were smaller incentives doled out to large numbers of actual prescribers. These took the form of more modest speakers' fees, fees for bogus clinical trials, and gifts in kind, such as lavish weekends at resorts.

194. Whether the kickbacks took the form of bogus speaker programs, honoraria, dinner and lunch meetings, cash payments or other similar schemes, the motive

was the same—to lock in patient referrals (i.e. prescriptions). The main targets of Organon's kickback schemes were doctors who had already prescribed a large amount of Organon drugs, were willing to prescribe Organon's drugs for off-label uses, or gave the representatives a listening ear.

i. Speaker Programs

195. Organon's speaker programs were frequently little more than poorly disguised kickback programs. These programs often lacked scientific, medical or educational value because they were largely used as vehicles for promoting off-label messages that were themselves misleading and unfounded.

196. In addition to these junkets, speakers were offered honoraria for their speaking engagements. The amount of speakers' honoraria varied. Organon's payments to these doctors greatly exceeded the fair market value and reasonable compensation ordinarily given to a speaker in a typical arms-length transaction, particularly as the presentations were often short and the audiences small.

ii. Advisory Boards

197. Organon used advisory boards as a way to funnel kickbacks to physicians. Organon would gather physicians for purposes of providing Organon with feedback on how to market its drugs. These advisory boards were open venues where off-label indications of Organon's drugs would be discussed. In exchange for participating in these events, the physicians would receive fees or honoraria.

iii. Preceptorships

198. Another Organon kickback scheme involved preceptorships, arrangements in which a doctor would allow a sales representative to shadow him or her for part of a day

(usually four to six hours). The representative then took that opportunity to promote Remeron to the physician. The promotion usually consisted of off-label messages. In exchange for allowing the preceptorship, the doctor would be paid a fee or honoraria for what amounted to a paid marketing campaign.

iv. Gifts in Kind

199. Organon often invited high prescribers to lavish events as a reward for their prescribing activity. Organon's choice of venues and excessive compensation reveal that the focus of these programs was on wining and dining doctors rather than on exchanging scientific and medical information.

v. Fees for Bogus Clinical Trials and Studies

200. Organon paid doctors fees for bogus clinical trials and studies in exchange for prescriptions. For example, Organon offered payment to physicians to participate in the Mature D study. Although Mature D took the form of a research clinical trial, it was, in fact, a marketing ploy designed to induce high-prescribing Remeron tablet general medical practitioners and psychiatrists to become comfortable prescribing Remeron SolTab.

201. These coupled campaigns to market Remeron in an off-label manner and to pay kickbacks to doctors to aid in that campaign and prescribe the drug directly resulted in dramatic increases in its profits for Remeron. In addition to tainting the prescriptions that arose out of such schemes, Organon's kickback and off-label marketing strategies raised the total cost assumed by Medicaid, because doctors, blinded by Organon's remunerations, prescribed Organon drugs that: (a) they would not have prescribed if not for the kickbacks; (b) were medically unnecessary and ineffective; or (c) were more expensive than alternative drugs that would otherwise have been prescribed.

XIII. INTRODUCTION TO RELATORS

A. Background of Relators

i. Jim Banigan

202. Jim Banigan is a seventeen-year veteran of Organon, where he worked until his termination on March 31, 2008. Banigan first came to Organon in 1991 as a sales representative. He was later promoted to become one of Organon's six original Regional Account Managers. He was then promoted to National Account Manager and began supervising and training other Regional Account Managers. After five years with Organon, Banigan became Manager of Government Accounts in 1996. In that position, he was responsible for Government Contracting and Government Contracts Administration, a position created for him and previously shared by several departments. Banigan became responsible for assuring that Organon drugs were on states' Medicaid formularies.

203. Banigan moved on to the Trade Department of Organon's National Accounts Division in early 2006, into an executive position in which he interacted with wholesalers, retail chains, and specialty pharmacies.

204. Although Banigan was not involved directly with the creation of the Medicaid scheme, he was a member of the leadership team within the same Managed Care department that developed the scheme and, as a result, had contemporaneous knowledge of it.

ii. Richard Templin

205. Richard Templin worked in management in the pharmaceutical arena for twelve years before joining Organon in March 2006. Templin, like Banigan, was an executive with Organon's Managed Markets Division. He was the Director of Government

Accounts at the time of his termination. He was hired by the Vice President of Managed Markets and reported to an Executive Leadership member until his termination on June 16, 2008.

206. When Templin first came to Organon, the Medicaid scheme was winding down; he nevertheless became aware of the scheme through the normal course of his job activities.

B. Relators' Discovery of Organon's Medicaid Scheme

207. Templin first became aware of the scheme to defraud Medicaid on Wednesday, September 27, 2006, while attending an Organon launch meeting at the Venetian Hotel in Las Vegas. Templin was having a conversation with John Maddox, an Executive Account Manager for Organon with responsibilities for both the Long Term Care and Managed Markets accounts. The topic of government compliance arose, and Maddox divulged the existence of a "non-compliant" program that provided him with a "get-out-of-jail-free card with Organon." Organon was undergoing significant management changes at that time and it was not uncommon for management and non-management staff to express concerns regarding their job security. Maddox did not offer any significant detail about the program. Templin did not pursue the topic further with Maddox that night, but decided to investigate further on his own.

208. Over the next few months, Templin was able to gather some information about the scheme Maddox had mentioned. He learned that the program centered on "marketing the spread" in the long-term care market and was focused exclusively on the product Remeron.

209. Templin broached the subject with a number of colleagues in late 2006 or early 2007, including Butch McKenna, Manager for Senior Care, National Accounts Division, who had created and managed the long-term care sales force. That sales force, Templin learned from McKenna, was set up specifically and with the expressed and written goal to implement the Medicaid scheme in the long-term care market. In addition, the long-term care sales force was responsible for working collaboratively with the Government Accounts department, led by Jim Banigan, to secure formulary access for Medicaid patients, many of whom were residing in their customers' nursing home facilities.

210. McKenna disclosed to Templin that the program to which Maddox had alluded, marketing the Remeron spread to pharmacy providers, was called "Time to Profit." In fact, McKenna possessed copies of a long-term care marketing binder that detailed the scheme. McKenna mentioned that Organon's compliance officer Rhetta Rierdan had contacted him earlier with a request to return to the home office all marketing materials that dealt with marketing the spread, and McKenna, wishing to keep the binder, had falsely responded that he no longer had it. McKenna believed that the officer sought to destroy any materials he gathered. McKenna echoed Maddox's belief that the program was illegal and that he considered his knowledge of the program to be his "golden ticket" to raise if anything were to go wrong for him at Organon. As a result, he planned to continue to hold onto all related materials at his home office.

211. Templin first spoke to Jim Banigan about the Medicaid scheme in early April of 2007, hoping that Banigan had heard of it. Banigan confirmed the existence of the scheme. Banigan related that, in November of 2003, just as the scheme was winding down,

Banigan heard about it from both McKenna, Director of Long Term Care Sales, and Maddox, Executive National Account Manager Long Term Care. Both discussions were prompted by changes in management and general concern over the leadership stability at Organon. McKenna had informed Banigan that he had direct knowledge of the Medicaid scheme and comprehensive documentation of marketing materials and other communications used to communicate to customers how to maximize their profits by influencing providers to prescribe Remeron. McKenna had explained that the Marketing Department conspired with McKenna's sales team to market Remeron almost purely based upon spread and profit potential. McKenna had told Banigan that he planned to hold his knowledge of the scheme "close to his vest" for the time being, but that if Organon attempted to "squeeze him out," he would use this evidence as his "insurance policy."

212. In a separate conversation with Maddox a day after Banigan heard about this scheme from McKenna, Maddox, too, implicated the Marketing Department for producing materials used to highlight how to maximize profit and spread. Maddox indicated that the Marketing Department had recently become aware that the risk associated with continuation of this marketing scheme was too high. Maddox, McKenna and the rest of the long-term care sales team erased any evidence within their computers of selling-on-the-spread presentations and profit calculators. While Organon does have a general file retention policy requiring accounts managers to routinely clean out their electronic files, Maddox did not indicate to Banigan whether these actions of file destruction were brought about under that policy or from recommendations by general counsel for Organon.

213. Banigan had never seen for himself the marketing materials described by McKenna and Maddox, but after speaking with Templin, he decided to look for copies of those materials. He eventually secured original copies of two binders from former Remeron Executive brand director, Steve Vorrius, who had kept the original materials in his home. One of the binders was entitled "Long Term Care Sale Training" and the other was entitled "Remeron SolTab Therapeutic Interchange Program." Both have been described at length in Section V of this Complaint. Banigan was not able to locate these binders internally at Organon. While Remeron-related marketing materials at Organon's offices are currently kept in a segregated document review area at Organon's offices for litigation purposes, Banigan gathered from Steve Vorrius, Executive Brand Director, that these materials may have never been divulged in the course of litigation. After reading through the binders and learning how blatantly Organon had promoted the spread–along with added incentives–in the long-term care segment of Remeron's business, Banigan and Templin located and reviewed the contracts for Remeron's significant long-term care customers and found that the contracts' terms evidenced the same types of incentives reflected in the promotional materials. Moreover, the addenda to the contracts and accompanying communications reflected that as pressures mounted within Organon to grow the Remeron Tablet/Remeron SolTab business and to thwart impending generic competition, off-invoice discounts migrated to rebates. That move toward rebates assisted long-term customers in masking their true acquisition costs. In particular, rebates were preferred among long-term care providers who operated businesses within states in which Medicaid agencies benchmarked reimbursement upon actual acquisition cost.

214. Further, Banigan and Templin realized that long-term care contracts had continuously been extended to guarantee maximum discounts. Those extensions would have required the cooperation of the sales, marketing, and account management groups. In addition, shared services such as legal, finance, and meeting planning would have had to be involved in order to secure approval and financial resources to support the scheme.

215. Banigan and Templin also located draft copies of both McKenna's and Maddox's 2001 business plans, which further evidence the promotion of "spread" and other financial incentives to pharmacy providers.

216. Thus, it was clear to Banigan and Templin by July of 2007 that Organon's upper management knew about the Medicaid scheme but wished to conceal its existence from Medicaid and others. Further, Organon had not disclosed the scheme's existence to Organon's putative purchaser, Schering, during the parties' then ongoing due diligence period. In fact, executives were hiding evidence of the scheme in their homes in order to shield it from destruction by the Compliance Department.

C. Retaliation of Relators Banigan and Templin

217. Organon and Schering took adverse employment actions against Banigan and Templin for investigating their drug-pricing practices. Both Banigan and Templin were terminated after questioning Organon's pricing practices.

i. Jim Banigan

218. As Manager of Government Accounts from 1996 until early 2006 (when Banigan was promoted to an executive position in the Trade Department of Organon's National Accounts Division), Banigan was responsible for government price calculations. During that time, Banigan performed government pricing calculations utilizing an

Organon-developed system that was unreliable and would sometimes generate incorrect calculations. Banigan complained repeatedly to Organon's management about this problem from about 1996 until 1999. In response, Organon eventually hired a third-party auditor, Envision Consulting Group ("Envision"), to audit its system. Even then, due to Organon's lack of financial commitment to diagnosing the cause of the system's calculation errors, Envision was able to offer only a quick and limited audit, relying largely on issue-spotting assistance from Organon employees such as Banigan. Although Envision provided Organon with a report regarding its findings, Banigan was never allowed to see the report. Banigan nevertheless learned from the Envision auditor that the audit found defects in Organon's pricing calculation system, confirming that it was unreliable. Beginning in early 2006, positioning itself for sale, Organon finally decided to spend the required money to hire a team of experts to set up a new government pricing system that could withstand an audit and survive the due diligence process of a corporate sale. As a result, the Organon-developed government pricing system was corrected by the third quarter of 2006, and a new system developed by outside experts was put into place in October 2007. Previous pricing errors were not corrected and were not reported to the federal or state Governments.

219. In the fall of 2007, following Schering Plough's decision to purchase Organon, Schering Plough began its due diligence review of Organon's government pricing area. Schering Plough hired the same auditor, Envision Consulting Group, to audit Organon's government pricing area. Strangely, throughout its due diligence work, Envision made only limited contact with Banigan, then Director of Trade, and Templin, then Director of Government Accounts. Moreover, Schering Plough carefully limited

Envision's audit to the most recent quarter calculations, which had been performed using Organon's revamped government pricing system. Thus, the audit inevitably failed to reveal the government pricing discrepancies stemming from the old system. Envision was well aware of the pricing discrepancies caused by the old calculation system, of course, and likely informed Schering Plough of these defects. Schering Plough purposefully requested Envision's audit to be limited to only the most recent quarter calculations in order to avoid having formal notice of any older defects.

220. In November 2007, shortly after Envision performed the audit and declared that there were limited or insignificant problems with the most recent quarter calculations, Schering Plough bought all shares of Organon BioSciences, the holding company for Organon's pharmaceutical operations. As a result of the sale, Organon's employees were required to apply for positions in Schering Plough. Banigan applied for two jobs for which he was qualified based on his prior experience at Organon: 1) Director of Specialty Pharmacy Markets, and 2) National Account Manager, a non-supervisory sales job. Schering Plough offered Banigan the lesser of the two positions, even though Schering Plough's management admitted that Banigan was the only candidate who met the job qualification posted for the Director of Specialty Pharmacy Markets position. On March 31, 2008, Schering Plough terminated Banigan, stating that there was no comparable position for him, even though he was qualified these open positions in the new company. Banigan was unable to accept the severance package that he was offered, because it encompassed a pledge affirming that he did not know of any fraud committed by the company.

ii. Richard Templin

221. Templin worked as the Director of Government Accounts at Organon from March 2006 until June 16, 2008. In fall 2007, Organon placed Templin on a team of individuals, referred to as the "clean team," reviewing the government pricing area as part of Schering Plough's due diligence review of Organon. The team included both an Organon section and a Schering Plough section, but each section communicated solely with and through the team leader, Envision, and not to each other.

222. Months into the due diligence period, Templin observed that Schering was neglecting to conduct any substantial due-diligence inquiry into government contracts. Templin took particular notice of Schering's election to hire Envision to audit only the most recent quarter. Concerned, Templin discussed his knowledge of the historical pricing practices—including Public Health Services contracts and recalculations of best price calculations based on problems with the Public Health Services contracts— with other Organon clean team members, including Jim Harmon, Vice President Managed Markets for Organon.

223. In February 2008, Templin notified Debbie Kane, Vice President of Finance for Schering Plough, of the need to report these practices in light of requirements in Schering Plough's Corporate Integrity Agreement. In response, Kane moved to have Templin terminated immediately and stated that "Senior Management would never approve of that."

224. Templin then reported the historical pricing discrepancies and practices to Schering Plough's Integrity Hotline on March 3, 2008. Within three weeks after Templin filed his complaint with Schering Plough's Integrity Hotline and had follow-up discussions with Schering Plough, Schering Plough placed Templin on administrative leave, which

lasted from March 25, 2008 through his termination on June 16, 2008. During his period of placement on administrative leave, Schering Plough discouraged Templin from coming into the office. In addition, on May 30, 2008, Schering Plough terminated Templin's Blackberry access. Templin's access to the office became so limited by the time of his termination that Schering Plough's Human Resources department was forced to contact Templin through the website www.Linkedin.com to inform him of his exit interview.

225. During his exit interview, Templin learned from Human Resources representatives, Beth Perrone and Dorine Hirtz-Ganz, that Envision had told Organon that Templin had claimed that he was himself responsible for the historical pricing problems involving the Public Health Services contracts. Perrone and Hirtz-Ganz added that such actions were against Schering Plough's policies and constituted the grounds for his termination. Contrary to their assertions, of course, the pricing actions taken by Templin were in accordance with Organon's policies and procedures and with the approval of Organon's senior management and legal department of Organon. Apparently worried that Templin would file suit under the False Claims Act, Schering-Plough offered Templin a severance package contingent on his release of certain claims, including an express provision requiring Templin to release any and all claims that could be asserted under the False Claims Act or under any state *qui tam* statute. Templin refused to sign this agreement and thus received no severance payment.

XIV. ACTIONABLE CONDUCT BY ORGANON, PHARMERICA, AND OMNICARE UNDER THE FALSE CLAIMS ACT

A. Applicable Law

i. The False Claims Act

226. This is an action to recover damages and civil penalties on behalf of the United States and Relators Banigan and Templin arising from the false or fraudulent statements, claims, and acts by Organon, PharMerica, and Omnicare made in violation of the False Claims Act, 31 U.S.C. §§ 3729–3732.

227. For conduct occurring before May 20, 2009, the False Claims Act ("FCA") provides that any person who:

(a) knowingly presents, or causes to be presented, to an officer or employee of the United States Government or a member of the Armed Forces of the United States a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the Government;

(c) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the Government.

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

228. For conduct occurring on or after May 20, 2009, the FCA provides that any person who:

(a) knowingly presents, or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to get a false or fraudulent claim paid (except that this language applies to all claims pending on or after June 7, 2008)

(c) conspires to defraud the Government by committing a violation of the FCA;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal material to an obligation to pay or transmit money or property to the Government.

is liable to the Government for a civil penalty of not less than $5,500 and not more than $11,000 for each such claim, plus three times the amount of damages sustained by the Government because of the false or fraudulent claim.

229. The FCA allows any persons having knowledge of a false or fraudulent claim against the Government to bring an action in Federal District Court for themselves and for the United States Government and to share in any recovery as authorized by 31 U.S.C. § 3730.

230. Based on these provisions, Relators Banigan and Templin, on behalf of the United States Government and the states of California, Connecticut, Delaware, Florida, Georgia, Hawaii, Illinois, Indiana, Louisiana, Michigan, Montana, Nevada, New Hampshire, New Jersey, New Mexico, New York, North Carolina, Oklahoma, Rhode Island, Tennessee, Texas, and Wisconsin, the Commonwealths of Massachusetts and Virginia, the District of Columbia, and the City of Chicago (collectively the "states") seek through this action to recover damages and civil penalties arising from Organon's causation of the submission of false claims to the federal and state governments. In this case, such claims were submitted to the federal Government for payment for Remeron Tablet and Remeron SolTab. Relators believe that the United States and the states have suffered significant damages as a result of false claims for payment for Remeron Tablet and Remeron SolTab.

231. There are no bars to recovery under 31 U.S.C. § 3730(e), and, or in the alternative, Relators are original sources as defined therein. Relators have direct and independent knowledge of the information on which the allegations are based, as required pursuant to 31 U.S.C. §§ 3730(b) and (e). Relators have voluntarily provided information, oral and/or written, and have sent disclosure statement(s) of all material evidence, information and documents related to this complaint, both before and after filing, to the Attorney General of the United States, the United States Attorneys for the Southern District of Texas and the District of Massachusetts, and the Attorneys General of the various states, commonwealths, and the District of Columbia.

ii. The Federal Anti-Kickback Statute

232. In pertinent part, the Anti-Kickback Statute provides:

> (b) Illegal remuneration
>
> 1. whoever knowingly and willfully solicits or receives any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind—
>
> (A) in return for referring an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) in return for purchasing, leasing, ordering, or arranging for or recommending purchasing, leasing, or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,

> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> 2. whoever knowingly and willfully offers or pays any remuneration (including any kickback, bribe, or rebate) directly or indirectly, overtly or covertly, in cash or in kind to any person to induce such person—
>
> (A) to refer an individual to a person for the furnishing or arranging for the furnishing of any item or service for which payment may be made in whole or in part under a Federal health care program, or
>
> (B) to purchase, lease, order or arrange for or recommend purchasing, leasing or ordering any good, facility, service, or item for which payment may be made in whole or in part under a Federal health care program,
>
> shall be guilty of a felony and upon conviction thereof, shall be fined not more than $25,000 or imprisoned for not more than five years, or both.
>
> 3. Paragraphs (1) and (2) shall not apply to—
>
> (A) a discount or other reduction in price obtained by a provider of services or other entity under a Federal health care program if the reduction in price is properly disclosed and appropriately reflected in the costs claimed or charges made by the provider or entity under a Federal health care program;

42 U.S.C. § 1320a-7b(b). Those who violate the statute also are subject to exclusion from participation in federal health care programs, and civil monetary penalties of up to

$50,000 per violation and up to three times the amount of remuneration paid. 42 U.S.C. § 1320a-7(b)(7) and 42 U.S.C. § 1320a-7a(a)(7).

233. The purpose of the Anti-Kickback Statute is to prohibit such activities in order to secure proper medical treatment and referrals and to limit unnecessary treatments, services, or goods that are based not on the needs of the patient but on improper incentives given to others, thereby limiting the patient's right to choose proper medical care and services. *See* Medicare and Medicaid Programs; Fraud and Abuse OIG Anti-Kickback Provisions, 54 Fed. Reg. 3088, 3089 (proposed Jan. 23, 1989) (to be codified 42 C.F.R. pt. 1001).

B. Fraudulent Conduct by Organon, PharMerica, and Omnicare Violates the FCA

i. Organon Caused Long-Term Care Pharmacy Providers to Submit False Claims by Offering Kickbacks and Long-Term Care Pharmacy Providers Solicited and Accepted Kickbacks in Violation of the Anti-Kickback Statute and the FCA

234. The Anti-Kickback Statute prohibits the offer or acceptance of remuneration to induce a physician to prescribe a drug. Organon violated the Anti-Kickback Statute by offering significant discounts and rebates to its GPO and long-term care pharmacy provider customers in exchange for prescriptions for Remeron Tablet and Remeron SolTab. Organon's 1999 and 2000 contracts with GPOs such as GeriMed, Managed Healthcare Associates, Owen and Committed Provider Services, provided for significant discounts and rebates on Remeron Tablet applicable only to the long-term care pharmacy provider members of these GPOs. Organon's 1999 and 2000 contracts with the most prominent GPOs, such as GeriMed, Managed Healthcare Associates, Owen and Committed Provider Services, provided long-term care pharmacy provider members with

8% to 14.8% "ramp-up" charge-back discounts for the first five months, followed by **8% to 15% chargeback discounts** after that, depending on the market share held by Remeron Tablet for that member of the GPO. These market-tier discounts were based on the performance of individual long-term care pharmacy providers, not the performance of the GPO as a whole. In exchange for these discounts, Organon required the long-term care pharmacy providers to promote Remeron Tablets to their individual pharmacies.

235. Beginning in late 2000 and early 2001, Organon began negotiating with long-term care pharmacy providers directly, offering new incentives in addition to the market share discounts already in place. Organon added ramp-up discounts, "conversion" rebates tied to conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, and "therapeutic interchange" bonuses conditioned on LTCPPs bestowing Remeron Tablet and Remeron SolTab with a "preferred" status and engaging in an active therapeutic interchange program. In addition, Organon moved from offering discounts to offering off-invoice rebates, allowing long-term care pharmacy providers to hide their true costs. Two long-term pharmacy providers, PharMerica and Omnicare, eventually agreed to contract directly with Organon; the others remained members of GPOs while individually negotiating contract terms.

236. In addition, to expand and maintain its market share for its drugs Remeron Tablet and Remeron SolTab, Organon offered and long-term care pharmacy providers, such as PharMerica, Omnicare, NeighborCare, NCS Healthcare, APS, and Sunscript, solicited kickbacks to purchase and recommend Remeron Tablet and Remeron SolTab and engage in therapeutic interchange programs for Remeron products. These kickbacks included, but were not limited to, data sharing agreements, research and educational grants,

support of annual meetings and continuing education programs, payment for advertising initiatives, offers of nominally-priced Remeron product, entertainment, gifts, and other inducements.

237. Organon's fraudulent schemes to induce customers to purchase its products and the solicitation and acceptance of kickbacks by PharMerica and Omnicare violated the Anti-Kickback Statute and the FCA, 31 U.S.C. § 3729 (a).

238. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the Government's payment decision.

239. Because of the illegal acts described above, Organon made millions of dollars in sales of Remeron Tablet and Remeron SolTab to Medicaid patients it would not otherwise have achieved. Additionally, because of the illegal acts described above, PharMerica and Omnicare made profits from the substitution of other drugs for Remeron Tablet and Remeron SolTab at Medicaid's expense. The ultimate submission by long-term care pharmacy providers of false claims to the state Medicaid programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Consequently, the states and the United States Government have suffered substantial damages.

ii. Organon Conspired with Its Long Term Care and GPO, Customers to Defraud Medicaid in Violation of the FCA

240. Organon and long-term care pharmacy providers, including PharMerica, Omnicare, and Sunscript, NCS Healthcare, NeighborCare, and American Pharmaceutical Services, as well as GPOs, entered into agreements and conspired with one another to submit false claims for reimbursement for Remeron Tablet and Remeron SolTab

prescriptions to state Medicaid programs and to receive reimbursement for these drugs to which the customers were not entitled.

241. As part of the scheme and agreement to obtain reimbursement for Remeron Tablet and Remeron SolTab prescriptions in violation of the state Medicaid programs' reimbursement policies, Organon and its pharmacy customers conspired and agreed to perform acts to effectuate the conspiracy.

242. As described more fully above, Organon's 1999 and 2000 contracts with GPOs provided for significant discounts and rebates on Remeron Tablet applicable only to the long-term care pharmacy provider members of these GPOs in exchange for the promotion of Remeron Tablets to their individual pharmacies.

243. Beginning in late 2000 and early 2001, Organon began offering new incentives in addition to the market share discounts already in place. Organon added ramp-up discounts, "conversion" rebates tied to conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, and "therapeutic interchange" bonuses conditioned on LTCPPs bestowing Remeron Tablet and Remeron SolTab with a "preferred" status and engaging in an active therapeutic interchange program. In addition, after complaints by long-term care pharmacy providers that these providers were passing through the discounts to the state Medicaid programs, Organon moved from offering discounts to rebates to allow long-term care pharmacy providers to hide their true costs.

244. Furthermore, Organon offered kickbacks in various forms to long-term care pharmacy providers in exchange for purchasing and recommending Remeron Tablet and Remeron SolTab and, in some cases, for engaging in therapeutic interchange programs for Remeron products. Organon's various kickback schemes included, but were not limited

to, data sharing agreements, research and educational grants, support of annual meetings and continuing education programs, payment for advertising initiatives, offers of nominally-priced Remeron product, entertainment, gifts, and other inducements.

245. In furtherance of the conspiracy, Organon, PharMerica, and Omnicare entered into long-term care contracts providing for financial incentives in the form of ramp-up discounts and rebates that were routinely extended beyond the initial offering period, conversion rebates, and therapeutic interchange bonuses. Organon's contracts with these providers and GPOs assured an increased amount of prescriptions for Remeron Tablet and Remeron SolTab and thereby a larger profit for all parties involved.

246. Moreover, Organon's long-term care pharmacy provider customers solicited kickbacks in the guise of corporate partnership programs from Organon to purchase Remeron Tablet and Remeron SolTab and convert prescriptions to Remeron.

247. In furtherance of the conspiracy, during the Remeron Medicaid scheme, compensation to PharMerica general managers and clinical directors was based in part upon the relative margin and opportunity to profit from Remeron Tablet and Remeron SolTab. In addition, PharMerica rewarded Organon Vendor of the Year in 2002 and Diamond Level for several years, for Organon's financial contributions to PharMerica's VIP program.

248. As they knew would be the case, Organon, PharMerica, and Omnicare's actions resulted in the submission to state Medicaid programs of false and fraudulent claims for reimbursement for Remeron Tablet and Remeron SolTab, violating the FCA, 31 U.S.C. § 3729 (a), and resulting in substantial damages to the United States.

iii. Organon Caused Retail, Mail-Order, and Managed Care Pharmacies to Submit False Claims

249. Organon engaged in a similar scheme to induce retail, mail-order and managed care pharmacies to convert Remeron Tablet prescriptions to Remeron SolTab prescriptions. The Anti-Kickback Statute prohibits the offer or acceptance of remuneration to induce a physician to prescribe a drug. Organon violated the Anti-Kickback Statute by offering kickbacks to retail, mail-order and managed care pharmacies for the sole purpose of encouraging conversion of Remeron Tablet prescriptions to Remeron SolTab prescriptions, rather than engaging in therapeutic interchange programs. These kickbacks took various forms, such as marketing the "spread" on Remeron SolTab versus the "spread" on Remeron Tablet at Medicaid's expense and other financial inducements.

250. Organon's fraudulent schemes to induce customers to purchase its products violated the Anti-Kickback Statute and the FCA, 31 U.S.C. § 3729 (a).

251. Given the structure of the health care systems, Organon's false statements, representations, and records had the potential to influence the Government's payment decision.

252. The ultimate submission by long-term care pharmacy providers of false claims to the state Medicaid programs was a foreseeable factor in the Government's loss, and a consequence of the scheme. Consequently, the states and the United States Government have suffered substantial damages.

iv. Organon Conspired with Its Retail, Mail-Order and Managed Care Pharmacy Customers to Defraud Medicaid in Violation of the FCA

253. Organon and its retail, mail-order, and managed care pharmacy customers entered into agreements and conspired with one another to submit false claims for reimbursement for Remeron Tablet and Remeron SolTab prescriptions to state Medicaid

programs and to receive reimbursement for these drugs to which the customers were not entitled.

254. As part of the scheme and agreement to obtain reimbursement for Remeron Tablet and Remeron SolTab prescriptions in violation of the state Medicaid programs' reimbursement policies, Organon and its retail, mail-order and managed care pharmacy customers conspired and agreed to perform acts to effectuate the conspiracy. Organon widely marketed the promise of better Medicaid reimbursement by virtue of SolTab's greater proportional "markup" between AWP and WAC.

255. As they knew would be the case, Organon and its retail, mail-order, and managed-care pharmacy customers' actions resulted in the submission to state Medicaid programs of false and fraudulent claims for reimbursement for Remeron Tablet and Remeron SolTab, violating the FCA, 31 U.S.C. § 3729 (a), and resulting in substantial damages to the United States.

v. Organon Intentionally Decreased Its Rebate Liability to State Medicaid Programs

256. In submitting AMP and best price figures to CMS for Remeron Tablet and Remeron SolTab prescriptions, Organon knowingly or with reckless disregard for the truth made or used a false record or statement to conceal, avoid, or decrease its rebate payments to the state Medicaid programs owed under its rebate agreements.

257. Specifically, under the terms of the rebate agreements between Organon and the state Medicaid programs, Organon was required to pay rebates, the amount of which was premised on calculations involving AMPs and best prices for Remeron Tablet and Remeron SolTab, which Organon reported quarterly to CMS.

258. Organon intentionally used massive and illegal discounts and rebates offered to GPOs and long-term care pharmacy providers to lower its AMP figures for Remeron Tablet and Remeron SolTab, resulting in a reduction of its rebate liability for Remeron Tablet and Remeron SolTab to the state Medicaid programs. In addition, Organon concealed its true "best price" from the Government by entering into separate agreements with long-term care pharmacy providers that essentially amounted to kickbacks. By failing to disclose these payments to Medicaid, Organon avoided reporting its true "best price" to Medicaid, thereby lowering its rebate liability to Medicaid.

259. Moreover, Organon avoided disclosing the true best price for Remeron Tablet and Remeron SolTab. For example, at different times, Organon offered to Omnicare and PharMerica substantial quantities of Remeron SolTab at nominal prices contingent upon Omnicare and PharMerica's purchase of similar quantities of Remeron SolTab at a contracted discounted rate. Organon intentionally excluded the nominal price transactions when it reported its best price, even though it was required under best price law to disclose these transactions because they hinged upon a further purchase by Omnicare and PharMerica.

260. In addition, Organon entered into an arrangement with Kaiser that effectively allowed Organon to prospectively buy down discounts on Remeron by urging Kaiser to permit a shift in discounts to another product in order to avoid reporting its true best price on Remeron. In 2001, Organon realized that the discounts on Remeron under its 1997 fixed-price contact with Kaiser were setting a best price. In order to avoid reporting this true best price, Organon entered into an arrangement with Kaiser to increase the price of Remeron under the contract in exchange for providing the same amount of discounts on

Zemuron, another Organon product with low Medicaid sales. In order to conceal the best price violation, Organon backdated the amendment and removed transactions for Remeron from its chargeback system. Organon continued to extend the discounts under this contract until at least 2004. Organon therefore failed to report its true best price.

261. Organon also failed to maintain its 340B program covered entities membership list. Organon then sold Remeron to non-covered entities at government pricing, which Organon failed to report as part of its best price reporting, knowing that the best price would be lower and result in larger rebate liability.

262. Moreover, because the federal government uses best price reporting to set prices for 340B entities and the Federal Supply Schedule, Organon's failure to report the true best price caused other federal purchasers, such as 340B entities, the Department of Defense, the Veterans' Administration, the Bureau of Prisons, and the Bureau of Indian Affairs, to pay higher prices for Remeron Tablet and Remeron SolTab,

263. Organon's intentional reduction of its reported AMPs for Remeron Tablet and Remeron SolTab and purposeful avoidance of reporting best prices violated the FCA, 31 U.S.C. § 3729 (a), and caused the federal and state governments to suffer substantial damages as a result.

vi. Organon's Off-Label Marketing Scheme Violated the FCA

264. Moreover, Organon violated the FDCA by distributing drugs, specifically Remeron Tablet and Remeron SolTab, that were misbranded. Organon's promotion of Remeron Tablet and Remeron and SolTab constituted illegal misbranding because the drugs' labeling was false or misleading, their labeling did not bear adequate directions for use, their labeling did not bear adequate warnings against use in children and those with

pathological conditions, and/or their labeling did not bear adequate warnings against unsafe dosage or methods of administration or application. Organon's conduct flies in the face of the guidances and regulations that pertain to off-label marketing.

265. In addition, upon information and belief, Organon purposefully manipulated drug compendia, such as DRUGDEX, through the use of false statements or records or material omissions and caused them in some cases to list desired off-label uses based on evidence that did not actually substantiate or fortify the uses with the intent of getting Medicaid to reimburse these off-label uses. Organon knew that its false marketing materials and false and misleading representations by its sales representatives would cause physicians to submit claims for fraudulent Medicaid reimbursement.

266. Organon's fraudulent scheme to aggressively and illegally market its drugs for off-label use and integrate illegal kickbacks into its off-label sales campaigns led to increased prescriptions for its drugs. Virtually all off-label prescriptions for these drugs for which Medicaid paid were a direct result of these illegal sales campaigns. Thus, these Medicaid claims for off-label prescriptions are tainted by the associated illegal kickbacks, as well as by Organon's "mislabeling" of its drugs. Organon's scheme violated the Anti-Kickback Statute and the FDA's prohibitions on the promotion of off-label uses, and therefore caused false claims to be submitted by long-term care pharmacy providers in violation of the FCA. By taking part in this fraudulent scheme, Organon repeatedly and with continued knowledge violated the False Claims Act, 31 U.S.C. § 3729 (a).

vii. Organon and Schering Plough Retaliated Against Banigan and Templin in Violation of the FCA

267. During and after Schering Plough's purchase of Organon, Banigan and Templin consistently raised questions to colleagues and management regarding the

reliability of Organon's government pricing computer systems and the likely fraud upon the Government resulting from that unreliability. In response, Schering Plough terminated Banigan and Templin in 2008. Banigan and Templin have thus suffered negative employment consequences and have suffered damages, now and in the future.

viii. Damages

268. Under the FCA and applicable law, Remeron Tablet and Remeron SolTab prescriptions resulting from Organon's fraudulent schemes should not have been submitted to state Medicaid programs. The ultimate submission by long-term care pharmacy providers and by retail, mail-order and managed care pharmacies pharmacists of false claims to the state Medicaid programs was a foreseeable factor in the Government's loss, and a consequence of the Defendants' fraudulent schemes.

269. In addition, Organon's actions caused Medicaid and other federal purchasers to pay an inflated price for Remeron Tablet and Remeron SolTab.

270. Furthermore, Organon's false reporting of its AMP and best price for Remeron Tablet and Remeron SolTab resulted in a reduced rebate paid to the state Medicaid programs.

271. Consequently, the states and the United States Government have suffered approximately $421.7 million in damages, which trebled is approximately $1.263 billion, stemming from improper Remeron Tablet and Remeron SolTab prescription costs.

XV. CAUSES OF ACTION

A. COUNT I - FALSE CLAIMS ACT (31 U.S.C. § 3729)

272. Relators reallege and hereby incorporate by reference each and every allegation contained in paragraphs 1 through 271 in this Complaint.

273. Based on the acts described above, Defendants knowingly violated one or more of the provisions of the FCA, 31 U.S.C. § 3729(a).

274. The United States Government paid the false and/or fraudulent claims.

275. Due to the Defendants' conduct, the United States Government has suffered substantial monetary damages.

B. COUNT II – RETALIATION (31 U.S.C. § 3730(H))

276. The *qui tam* Relators reallege and incorporate by reference each and every allegation contained in paragraphs 1 through 275 of this Complaint.

277. In violation of the False Claims Act § 3730(h), Organon and Schering Plough took negative employment actions against Relators in response to their investigation and initiation of this claim.

278. As a result of Organon and Schering Plough's conduct, the Relators suffered negative employment consequences and have suffered damages, now and in the future.

RELIEF

279. On behalf of the United States Government, Relators seek to receive monetary damages equal to three times that suffered by the United States Government. In addition, Relators seek to receive all civil penalties on behalf of the United States Government in accordance with the False Claims Act.

280. The *qui tam* Relators seek to receive on their own behalf all monetary damages to which they are entitled for Organon and Schering Plough's retaliatory conduct against them. In addition, the Relators seek punitive damages in their own behalf.

281. Relators seek to be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d) of the False Claims Act.

282. Relators seek to be awarded all costs and expenses for this action, including attorneys' fees and court costs.

283. Relators seek to be awarded all other relief on behalf of Relators or the United States Government to which either may be entitled and that the Court deems just and proper.

PRAYER

WHEREFORE, Relators pray that this Court enter judgment on behalf of Relators and against Defendants for the following:

a. Damages in the amount of three (3) times the actual damages suffered by the United States Government as a result of Defendants' conduct;

b. Civil penalties against Defendants up to $11,000 for each violation of 31 U.S.C. § 3729;

c. Relators be awarded the maximum amount allowed pursuant to 31 U.S.C. § 3730(d);

d. Relators be awarded all costs and expenses of this litigation, including attorneys' fees and costs of court;

e. Relators' individual damages;

f. Pre-judgment interest at the highest rate allowed by law to the Relators for the retaliatory conduct by Organon and Schering Plough;

g. Punitive damages to the Relators for the retaliatory conduct by Organon and Schering Plough; and

h. All other relief on behalf of Relators or the United States Government to which either may be entitled and that the Court deems just and proper.

C. COUNT III - CALIFORNIA FALSE CLAIMS ACT

284. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

285. This is a *qui tam* action brought by Relators and the State of California to recover treble damages and civil penalties under the California False Claims Act, Cal. Gov't. Code § 12650 *et seq.*

286. Cal. Gov't Code § 12651(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the state or of any political division thereof, a false claim for payment or approval;
> (2) knowingly makes, uses, or causes to be made or used a false record or statement to get a false claim paid or approved by the state or by any political subdivision;
> (3) conspires to defraud the state or any political subdivision by getting a false claim allowed or paid by the state or by any political subdivision.
>
> ***
>
> (7) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

287. Organon, Omnicare and PharMerica knowingly violated Cal. Gov't Code § 12651(a) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the California Anti-Kickback Statutes (Cal. Bus. & Prof. Code §§ 650-650.1 and Cal. Welf. & Inst. Code §14107.2), as described herein.

288. The State of California, by and through the California Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

289. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of California's payment decision.

290. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of California's loss, and a consequence of the scheme.

291. As a result of the Defendants' violations of Cal. Gov't Code §12651(a), the State of California has been damaged.

292. There are no bars to recovery under Cal. Gov't Code §12652(d)(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Cal. Gov't Code § 12652(c) on behalf of themselves and the State of California.

293. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of California in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF CALIFORNIA:

(1) Three times the amount of actual damages which the State of California has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of up to $11,000 for each false claim that Organon, Omnicare and PharMerica presented or caused to be presented to the State of California;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Cal. Gov't Code § 12652 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

D. COUNT IV - DELAWARE FALSE CLAIMS AND REPORTING ACT

294. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

295. This is a *qui tam* action brought by Relators and the State of Delaware to recover treble damages and civil penalties under the Delaware False Claims and Reporting Act, Title 6, Chapter 12 of the Delaware Code.

296. 6 Del. C. § 1201(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, directly or indirectly, to an officer or employee of the Government a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, directly or indirectly, a false record or statement to get a false or fraudulent claim paid or approved; or

(3) conspires to defraud the Government by getting a false or fraudulent claim allowed or paid.

***

(7) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

297. Organon, Omnicare, and PharMerica knowingly violated 6 Del. C. § 1201(a) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Delaware Anti-Kickback Statute (31 Del. C. § 1005), as described herein.

298. The State of Delaware, by and through the Delaware Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

299. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Delaware's payment decision.

300. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Delaware's loss, and a consequence of the scheme.

301. .As a result of the Defendants' violations of 6 Del. C. § 1201(a), the State of Delaware has been damaged.

302. There are no bars to recovery under 6 Del. C. § 1206(c), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 6 Del. C. § 1203(b) on behalf of themselves and the State of Delaware.

303. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Delaware in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare, and PharMerica:

To the STATE OF DELAWARE:

(1) Three times the amount of actual damages which the State of Delaware has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare, and PharMerica caused to be presented to the State of Delaware;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to 6 Del. C. § 1205, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

E. COUNT V - DISTRICT OF COLUMBIA PROCUREMENT REFORM AMENDMENT ACT

304. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

305. This is a *qui tam* action brought by Relators and the District of Columbia to recover treble damages and civil penalties under the District of Columbia Procurement Reform Amendment Act, D.C. Code § 2-308.13 *et seq.*

306. D.C. Code § 2-308.14(a) provides liability for any person who-

> (1) knowingly presents, or causes to be presented, to an officer or employee of the District a false claim for payment or approval;
>
> (2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false claim paid or approved by the District;
>
> (3) conspires to defraud the District by getting a false claim allowed or paid by the District;
>
> ***
>
> (7) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

307. Organon, Omnicare, and PharMerica knowingly violated D.C. Code § 2-308.14(a) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the District of Columbia Anti-Kickback Statute (D.C. Code § 4-802), as described herein.

308. The District of Columbia, by and through the District of Columbia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

309. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the District of Columbia's payment decision.

310. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the District of Columbia's loss, and a consequence of the scheme.

311. As a result of the Defendants' violations of D.C. Code § 2-308.14(a) the District of Columbia has been damaged.

312. There are no bars to recovery under D.C. Code §2-308.15(c)(2), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to D.C. Code § 2-308.15(b) on behalf of themselves and the District of Columbia.

313. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the District of Columbia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon. Omnicare and PharMerica:

To the DISTRICT OF COLUMBIA:

(1) Three times the amount of actual damages which the District of Columbia has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare, and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the District of Columbia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to D.C. Code § 2-308.15(f) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

F. COUNT VI - FLORIDA FALSE CLAIMS ACT

314. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

315. This is a *qui tam* action brought by Relators and the State of Florida to recover treble damages and civil penalties under the Florida False Claims Act, Fla. Stat. § 68.081 *et seq.*

316. Fla. Stat. § 68.082(2) provides liability for any person who-

1. knowingly presents, or causes to be presented, to an officer or employee of an agency a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by an agency;

3. conspires to submit a false claim to an agency or to deceive an agency for the purpose of getting a false or fraudulent claim allowed or paid;

4. knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

317. Organon, Omnicare and PharMerica knowingly violated Fla. Stat. § 68.082(2) from at least 1999 to 2005, including by their violations the Federal Anti-Kickback Statute and the Florida Anti-Kickback Statute (Fla. Stat. § 409.920), as described herein.

318. The State of Florida, by and through the Florida Medicaid program and other state healthcare programs, paid the false and/or fraudulent claims.

319. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Florida's payment decision.

320. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Florida's loss, and a consequence of the scheme.

321. As a result of the Defendant's violations of Fla. Stat. § 68.082(2), the State of Florida has been damaged.

322. There are no bars to recovery under Fla. Stat. § 68.087(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Fla. Stat. § 68.083(2) on behalf of themselves and the State of Florida.

323. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Florida in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF FLORIDA:

(1) Three times the amount of actual damages which the State of Florida has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Florida;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Fla. Stat. § 68.085 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

G. COUNT VII – GEORGIA FALSE CLAIMS ACT

324. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

325. This is a *qui tam* action brought by Relators and the State of Georgia to recover treble damages and civil penalties under the Georgia False Claims Act, Georgia Code Ann. § 49-4-168 *et seq.*

326. Georgia Code Ann. § 49-4-168.1 provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

327. Organon, Omnicare and PharMerica knowingly violated Georgia Code Ann. § 49-4-168.1 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute, as described herein.

328. The State of Georgia, by and through the Georgia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

329. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Georgia's payment decision.

330. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Georgia's loss, and a consequence of the scheme.

331. As a result of the Defendants' violations of Georgia Code Ann. § 49-4-168.1, the State of Georgia has been damaged.

332. There are no bars to recovery under Georgia Code Ann. § 49-4-168.2, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Georgia Code Ann. § 49-4-168.1 on behalf of themselves and the State of Georgia.

333. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Georgia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF GEORGIA:

(1) Three times the amount of actual damages which the State of Georgia has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Georgia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Georgia Code Ann. § 49-4-168.2 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relator incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

H. COUNT VIII - HAWAII FALSE CLAIMS ACT

334. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

335. This is a *qui tam* action brought by Relators and the State of Hawaii to recover treble damages and civil penalties under the Hawaii False Claims Act, Haw. Rev. Stat. § 661-21 *et seq*.

336. Haw. Rev. Stat. § 661-21(a) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(3) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

337. Organon, Omnicare and PharMerica knowingly violated Haw. Rev. Stat. §661-21(a) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Hawaii Anti-Kickback Statute (Haw. Rev. Stat. § 346-43.5), as described herein.

338. The State of Hawaii, by and through the Hawaii Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

339. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Hawaii's payment decision.

340. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to

the state Medicaid programs was a foreseeable factor in the State of Hawaii's loss, and a consequence of the scheme.

341. As a result of the Defendants' violations of Haw. Rev. Stat. § 661-21(a), the State of Hawaii has been damaged.

342. There are no bars to recovery under Haw. Rev. Stat. § 661-28, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Haw. Rev. Stat. § 661-25(a) on behalf of themselves and the State of Hawaii.

343. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Hawaii in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF HAWAII:

(1) Three times the amount of actual damages which the State of Hawaii has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Hawaii;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Haw. Rev. Stat. §661-27 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

I. COUNT IX - ILLINOIS WHISTLEBLOWER REWARD AND PROTECTION ACT

344. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

345. This is a *qui tam* action brought by Relators and the State of Illinois to recover treble damages and civil penalties under the Illinois Whistleblower Reward and Protection Act, 740 ILCS 175 *et seq*.

346. 740 ILCS 175/3(a) provides liability for any person who-

1. knowingly presents, or causes to be presented, to an officer or employee of the State or a member of the Guard a false or fraudulent claim for payment or approval;

2. knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

3. conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

4. knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the state or to any political subdivision.

347. Organon, Omnicare and PharMerica knowingly violated 740 ILCS 175/3(a) from at least 1999 to 2005, including by their violations of the Federal Anti-

Kickback Statute and the Illinois Anti-Kickback Statute (305 ILCS 5/8A-3(b)), as described herein.

348. The State of Illinois, by and through the Illinois Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

349. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Illinois's payment decision.

350. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Illinois's loss, and a consequence of the scheme.

351. As a result of the Defendants' violations of 740 ILCS 175/3(a), the State of Illinois has been damaged.

352. There are no bars to recovery under 740 ILCS 175/4(e)(4), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to 740 ILCS 175/3(b) on behalf of themselves and the State of Illinois.

353. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Illinois in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF ILLINOIS:

(1) Three times the amount of actual damages which the State of Illinois has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Illinois;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to 740 ILCS 175/4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

J. COUNT X – INDIANA FALSE CLAIMS ACT

354. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

355. This is a *qui tam* action brought by Relators and the State of Indiana to recover treble damages and civil penalties under the Indiana False Claims Act, Ind. Code §5-11-5.5-1 *et seq*.

356. Ind. Code §5-11-5.5-1(b) provides liability for any person who-

1. presents a false claim to the state for payment or approval;
2. makes or uses a false record or statement to obtain payment or approval of a false claim from the state;

***

6. makes or uses a false record or statement to avoid an obligation to pay or transmit property to the state
7. conspires with another person to perform an act described in subdivisions (1) through (6).

357. Organon, Omnicare and PharMerica knowingly violated Ind. Code §5-11-5.5-1(b) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Indiana Anti-Kickback Statute (Ind. Code § 12-15-24-2), as described herein.

358. The State of Indiana, by and through the Indiana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

359. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Indiana's payment decision.

360. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Indiana's loss, and a consequence of the scheme.

361. As a result of the Defendants' violations of Ind. Code § 5-11-5.5-1(b), the State of Indiana has been damaged.

362. There are no bars to recovery under Ind. Code § 5-11-5.5-7(f), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Ind. Code §5-11-5.5-1(b) on behalf of themselves and the State of Indiana.

363. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Indiana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF INDIANA:

(1) Three times the amount of actual damages which the State of Indiana has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Indiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Ind. Code §5-11-5.5-6(a) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

K. COUNT XI - LOUISIANA MEDICAL ASSISTANCE PROGRAMS INTEGRITY LAW

364. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

365. This is a *qui tam* action brought by Relators and the State of Louisiana to recover treble damages and civil penalties under the Louisiana Medical Assistance Programs Integrity Law, La. Rev. Stat. Ann.§ 46:437.1 *et seq.*

366. La. Rev. Stat. Ann. § 46:438.3 provides-

(a) No person shall knowingly present or cause to be presented a false or fraudulent claim;

(b) No person shall knowingly engage in misrepresentation to obtain, or attempt to obtain, payment from medical assistance program funds; and

(c) No person shall conspire to defraud, or attempt to defraud, the medical assistance programs through misrepresentation or by obtaining, or attempting to obtain, payment for a false or fraudulent claim.

367. Organon, Omnicare and PharMerica knowingly violated La. Rev. Stat. Ann. § 46:438.3 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Louisiana Anti-Kickback Statute (La. Rev. Stat. Ann. § 46:438.2(A)), as described herein.

368. The State of Louisiana, by and through the Louisiana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

369. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Louisiana's payment decision.

370. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Louisiana's loss, and a consequence of the scheme.

371. As a result of the Defendants' violations of La. Rev. Stat. Ann. § 46:438.3 the State of Louisiana has been damaged.

372. There are no bars to recovery under La. Rev. Stat. Ann. § 46:439.1(E), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to La. Rev. Stat. Ann. § 46:439.1(A) on behalf of themselves and the State of Louisiana.

373. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Louisiana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF LOUISIANA:

(1) Three times the amount of actual damages which the State of Louisiana has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Louisiana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to La. Rev. Stat. § 46:439.4(A) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

L. COUNT XII - MASSACHUSETTS CLAIMS ACT

374. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

375. This is a *qui tam* action brought by Relators and the Commonwealth of Massachusetts for treble damages and penalties under Massachusetts False Claims Act, Mass. Gen. Laws Ann. 12 § 5(A) *et seq.*

376. Mass. Gen. Laws Ann. 12 § 5B provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid, or decrease an obligation to pay or to transmit money or property to the commonwealth or political subdivision thereof.

377. Organon, Omnicare and PharMerica knowingly violated Mass. Gen. Laws Ann. 12 § 5B from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Massachusetts Anti-Kickback Statute (Mass. Gen. Laws Ann. 118E §41), as described herein.

378. The Commonwealth of Massachusetts, by and through the Massachusetts Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

379. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the Commonwealth of Massachusetts's payment decision.

380. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the Commonwealth of Massachusetts's loss, and a consequence of the scheme.

381. As a result of the Defendants' violations of Mass. Gen. Laws Ann. 12 § 5B, the Commonwealth of Massachusetts has been damaged.

382. There are no bars to recovery under Mass. Gen. Laws Ann. 12 § 5G, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mass. Gen. Laws Ann. 12 § 5C(2) on behalf of themselves and the Commonwealth of Massachusetts.

383. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Massachusetts in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the COMMONWEALTH OF MASSACHUSETTS:

(1) Three times the amount of actual damages which the Commonwealth of Massachusetts has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the Commonwealth of Massachusetts;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Mass. Gen. Laws Ann.12, §5F and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

M. COUNT XIII - MICHIGAN CLAIMS ACT

384. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

385. This is a *qui tam* action brought by Relators and the State of Michigan for treble damages and penalties under Michigan False Claims Act, Mich. Comp. L. § 400.601 *et seq.*

386. Mich. Comp. L. §§ 400.603, 400.606 and 400.607 provides liability for any person who-

(1) knowingly makes or causes to be made a false statement or false representation of a material fact for use in determining rights to a Medicaid benefit;

(2) knowingly makes or presents or causes to be made or presented to an employee or officer of this state claim under Medicaid;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim.

387. Organon, Omnicare and PharMerica knowingly violated Mich. Comp. L. §§ 400.603, 400.606 and 400.607 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Michigan Anti-Kickback Statute (Mich. Comp. Laws § 400.604), as described herein.

388. The State of Michigan, by and through the Michigan Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

389. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Michigan's payment decision.

390. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Michigan's loss, and a consequence of the scheme.

391. As a result of the Defendants' violations of Mich. Comp. L. §§ 400.603, 400.606 and 400.607, the State of Michigan has been damaged.

392. There are no bars to recovery under Mich. Comp. L. § 400.610a(13), and, or in the alternative, Relators are original sources as defined therein. Relators are private

persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mich. Comp. L. § 400.610a(9) on behalf of themselves and the State of Michigan.

393. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Michigan in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF MICHIGAN:

(1) Three times the amount of actual damages which the State of Michigan has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Michigan;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Mich. Comp. L. §400.610a(9) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

N. COUNT XIV - MONTANA FALSE CLAIMS ACT

394. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

395. This is a *qui tam* action brought by Relators and the State of Montana for treble damages and penalties under Montana False Claims Act, Mont. Code Ann. § 17-8-401 *et seq.*

396. Mont. Code Ann. § 17-8-403(1) provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

397. Organon, Omnicare and PharMerica knowingly violated Mont. Code Ann. § 17-8-403(1) from at least 1999 to 2005, including by their violations of federal and state laws, including the Federal Anti-Kickback Statute and the Montana Anti-Kickback Statute (Mont. Code Ann § 45-6-313), as described herein.

398. The State of Montana, by and through the Montana Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

399. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Montana's payment decision.

400. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Montana's loss, and a consequence of the scheme.

401. As a result of the Defendants' violations of Mont. Code Ann. § 17-8-403(1), the State of Montana has been damaged.

402. There are no bars to recovery under Mont. Code Ann. § 17-8-403(5)(c), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Mont. Code Ann. § 17-8-410 on behalf of themselves and the State of Montana.

403. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Montana in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF MONTANA:

(1) Three times the amount of actual damages which the State of Montana has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Montana;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Mont. Code Ann. § 17-8-410 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

O. COUNT XV- NEVADA FALSE CLAIMS ACT

404. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

405. This is a *qui tam* action brought by Relators and the State of Nevada to recover treble damages and civil penalties under the Nevada False Claims Act, N.R.S. § 357.010, *et seq.*

406. N.R.S. § 357.040(1) provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the state or any political subdivision thereof;

(3) conspires to defraud the state or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

407. Organon, Omnicare and PharMerica knowingly violated N.R.S. § 357.040(1) from at least 1999 to 2005, including by their violations of the Federal Anti-

Kickback Statute and the Nevada Anti-Kickback Statute (N.R.S. § 422.560), as described herein.

408. The State of Nevada, by and through the Nevada Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

409. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Nevada's payment decision.

410. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Nevada's loss, and a consequence of the scheme.

411. As a result of the Defendants' violations of N.R.S. § 357.040(1) the State of Nevada has been damaged.

412. There are no bars to recovery under N.R.S. § 357.100, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.R.S. § 357.080(1) on behalf of themselves and the State of Nevada.

413. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Nevada in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF NEVADA:

(1) Three times the amount of actual damages which the State of Nevada has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $2,000 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Nevada;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to N.R.S. § 357.210 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

P. COUNT XVI – NEW HAMPSHIRE MEDICAID FRAUD AND FALSE CLAIMS ACT

414. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

415. This is a *qui tam* action brought by Relators and the State of New Hampshire to recover treble damages and civil penalties under the New Hampshire Medicaid Fraud and False Claims Act, N.H. Rev. Stat. Ann. § 167:61 *et. seq.*

416. N.H. Rev. Stat. Ann. §167:61-b(I) provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the state or any political subdivision thereof;

(3) conspires to defraud the state or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

417. Organon, Omnicare and PharMerica knowingly violated N.H. Rev. Stat. Ann. §167:61-b(I) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute as described herein.

418. The State of New Hampshire, by and through the New Hampshire Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

419. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of New Hampshire's payment decision.

420. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of New Hampshire's loss, and a consequence of the scheme.

421. As a result of the Defendants' violations of N.H. Rev. Stat. Ann. §167:61(I), the State of New Hampshire has been damaged.

422. There are no bars to recovery under N.H. Rev. Stat. Ann. § 167:61-e(III)(d), and, or in the alternative, Relators are original sources as defined therein.

Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.H. Rev. Stat. Ann. §167:61-e on behalf of themselves and the State of New Hampshire.

423. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Hampshire in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF NEW HAMPSHIRE:

(1) Three times the amount of actual damages which the State of New Hampshire has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,000 and not more than $10,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of New Hampshire;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to N.H. Rev. Stat. Ann. §167:61-e and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Q. COUNT XVII - NEW JERSEY FALSE CLAIMS ACT

424. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

425. This is a qui tam action brought by Relators and the State of New Jersey to recover treble damages and civil penalties under the New Jersey False Claims Act, N.J. Stat. Ann. §§ 2A:32-C1–2A:32-C18.

426. N.J. Stat. Ann. § 2A:32C-3 provides liability for any person who-

(a) knowingly presents or causes to be presented to an employee, officer or agent of the State, or to any contractor, grantee, or other recipient of State funds, a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used a false record or statement to get a false or fraudulent claim paid or approved by the State;

(c) conspires to defraud the State by getting a false or fraudulent claim allowed or paid by the State.

427. Organon, Omnicare and PharMerica knowingly violated N.J. Stat. Ann. § 2A:32C-3 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute, as described herein.

428. The State of New Jersey, by and through the New Jersey Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

429. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of New Jersey's payment decision.

430. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of New Jersey's loss, and a consequence of the scheme.

431. As a result of the Defendants' violations of N.J. Stat. Ann. § 2A:32C-3, the State of New Jersey has been damaged.

432. There are no bars to recovery under N.J. Stat. Ann. § 2A:32C-9(c), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.J. Stat. Ann. § 2A:32C-5(b) on behalf of themselves and the State of New Jersey.

433. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Jersey in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF NEW JERSEY:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of New Mexico;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to N.J. Stat. Ann. § 2A:32C-37 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

R. COUNT XVIII - NEW MEXICO MEDICAID FALSE CLAIMS ACT

434. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

435. This is a *qui tam* action brought by Relators and State of New Mexico to recover treble damages and civil penalties under the New Mexico Medicaid False Claims Act, N.M. Stat. Ann. § 27-14-1 *et seq.*

436. N.M. Stat. Ann. § 27-14-4 provides liability for any person who-

(1) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that such claim is false or fraudulent;

(2) presents, or causes to be presented, to the state a claim for payment under the Medicaid program knowing that the person receiving a Medicaid benefit or payment is not authorized or is not eligible for a benefit under the Medicaid program;

(3) makes, uses or causes to be made or used a record or statement to obtain a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

(4) conspires to defraud the state by getting a claim allowed or paid under the Medicaid program knowing that such claim is false or fraudulent;

(5) knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

437. Organon, Omnicare and PharMerica knowingly violated N.M. Stat. Ann. § 27-14-4 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the New Mexico Anti-Kickback Statute (N.M. Stat Ann. § 30-44-7), as described herein.

438. The State of New Mexico, by and through the State of New Mexico Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

439. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of New Mexico's payment decision.

440. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of New Mexico's loss, and a consequence of the scheme.

441. As a result of the Defendants' violations of N.M. Stat. Ann. § 27-14-4 the State of New Mexico has been damaged.

442. There are no bars to recovery under N.M. Stat. Ann. § 27-14-10(C), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.M. Stat. Ann. § 27-14-7 on behalf of themselves and the State of New Mexico

443. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New Mexico in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF NEW MEXICO:

(1) Three times the amount of actual damages which the State of New Mexico has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of New Mexico;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to N.M. Stat. Ann. § 27-14-4 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

S. COUNT XIX- NEW YORK FALSE CLAIMS ACT

444. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

445. This is a *qui tam* action brought by Relators and State of New York to recover treble damages and civil penalties under the New York False Claims Act, Bill S02108, § 187 *et seq.* (effective April 2007).

446. Bill S02108, § 189 provides liability for any person who-

(1) knowingly presents, or causes to be presented, a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to obtain payment or approval of a claim by the commonwealth or any political subdivision thereof;

(3) conspires to defraud the commonwealth or any political subdivision thereof through the allowance or payment of a fraudulent claim;

(4) knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

447. Organon, Omnicare and PharMerica knowingly violated Bill S02108 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute, as described herein.

448. The State of New York, by and through the State of New York Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

449. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of New York's payment decision.

450. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of New York's loss, and a consequence of the scheme.

451. As a result of the Defendants' violations of Bill S02108 the State of New York has been damaged.

452. There are no bars to recovery under Bill S02108, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Bill S02108 on behalf of themselves and the State of New York.

453. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of New York in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF NEW YORK:

(1) Three times the amount of actual damages which the State of New York has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $6,000 and not more than $12,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of New York;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Bill S02108 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

T. COUNT XX - OKLAHOMA FALSE CLAIMS ACT

454. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

455. This is a *qui tam* action brought by Relators and the State of Oklahoma to recover treble damages and civil penalties under the Oklahoma Medicaid False Claims Act, Oklahoma S.B. 889, 2007 O.S.L. 137.

456. S.B. 889, 2007 O.S.L. 137 provides liability for any person who-

(a) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

(b) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

(c) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;

(d) knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

457. Organon, Omnicare and PharMerica knowingly violated S.B. 889, 2007 O.S.L. 137 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Oklahoma Anti-Kickback Statute (56 Okla. Stat. Ann. § 1005, as described herein.

458. The State of Oklahoma, by and through the Oklahoma Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

459. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Oklahoma's payment decision.

460. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Oklahoma's loss, and a consequence of the scheme.

461. As a result of the Defendants' violations of S.B. 889, 2007 O.S.L. 137, the State of Oklahoma has been damaged.

462. There are no bars to recovery under S.B. 889, 2007 O.S.L. 137, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to S.B. 889, 2007 O.S.L. 137 on behalf of themselves and the State of Oklahoma.

463. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Oklahoma in the operation of its Medicaid program.

WHEREFORE, Relators respectfully requests this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF OKLAHOMA:

(1) Three times the amount of actual damages which the State of Oklahoma has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and

PharMerica caused to be presented to the State of Oklahoma;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to S.B. 889, 2007 O.S.L. 137, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

U. COUNT XXI - RHODE ISLAND FALSE CLAIMS ACT

464. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

465. This is a *qui tam* action brought by Relators and the State of Rhode Island to recover treble damages and civil penalties under the Rhode Island State False Claims Act, R.I. Gen. Laws § 9-1.1-1 *et seq.*

466. R.I. Gen. Laws § 9-1.1-3 provides liability for any person who-

(a) knowingly presents, or causes to be presented, to an officer or employee of the state or a member of the guard a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the state;

(c) conspires to defraud the state by getting a false or fraudulent claim allowed or paid.

467. Organon, Omnicare and PharMerica knowingly violated R.I. Gen. Laws § 9-1.1-3 from at least 1999 to 2005, including by their violations of the Federal Anti-

Kickback Statute and the Rhode Island Anti-Kickback Statutes (R.I. Gen Laws 5-48.1-3 and 40-8.2-3), as described herein.

468. The State of Rhode Island, by and through the Rhode Island Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

469. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Rhode Island's payment decision.

470. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Rhode Island's loss, and a consequence of the scheme.

471. As a result of the Defendants' violations of R.I. Gen. Laws § 9-1.1-3, the State of Rhode Island has been damaged.

472. There are no bars to recovery under R.I. Gen. Laws § 9-1.1-4(e)(3), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to R.I. § 9-1.1-4(b) on behalf of themselves and the State of Rhode Island.

473. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Rhode Island in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF RHODE ISLAND:

(1) Three times the amount of actual damages which the State of Rhode Island has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Rhode Island;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to R.I. Gen. Laws § 9-1.1-4(d) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

V. Count XXII - Tennessee False Claims Act

474. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

475. This is a *qui tam* action brought by Relators and the State of Tennessee to recover treble damages and civil penalties under the Tennessee Medicaid False Claims Act, Tenn. Code Ann. § 71-5-181 *et seq.*

476. § 71-5-182(a)(1) provides liability for any person who-

(a) presents, or causes to be presented to the state, a claim for payment under the Medicaid program knowing such claim is false or fraudulent;

(b) makes or uses, or causes to be made or used, a record or statement to get a false or fraudulent claim under the Medicaid program paid for or approved by the state knowing such record or statement is false;

(c) conspires to defraud the State by getting a claim allowed or paid under the Medicaid program knowing such claim is false or fraudulent;

(d) knowingly making, using, or causing to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

477. Organon, Omnicare and PharMerica knowingly violated Tenn. Code Ann. § 71-5-182(a)(1) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Tennessee Anti-Kickback Statute (Tenn. Code Ann. § 71-5-182), as described herein.

478. The State of Tennessee, by and through the Tennessee Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

479. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Tennessee's payment decision.

480. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Tennessee's loss, and a consequence of the scheme.

481. As a result of the Defendants' violations of Tenn. Code Ann. § 71-5-182(a)(1), the State of Tennessee has been damaged.

482. There are no bars to recovery under Tenn. Code Ann. § 71-5-183(e)(2), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint,

who have brought this action pursuant to Tenn. Code Ann. § 71-5-183(a)(1) on behalf of themselves and the State of Tennessee.

483. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Tennessee in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF TENNESSEE:

(1) Three times the amount of actual damages which the State of Tennessee has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Tennessee;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Tenn. Code Ann. § 71-5-183(c) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

W. COUNT XXIII - TEXAS FALSE CLAIMS ACT

484. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

485. This is a *qui tam* action brought by Relators and the State of Texas to recover double damages and civil penalties under V.T.C.A. Hum. Res. Code § 36.001 *et seq.*

486. V.T.C.A. Hum. Res. Code § 36.002 provides liability for any person who-

(1) knowingly or intentionally makes or causes to be made a false statement or misrepresentation of a material fact:

(a) on an application for a contract, benefit, or payment under the Medicaid program; or

(b) that is intended to be used to determine its eligibility for a benefit or payment under the Medicaid program.

(2) knowingly or intentionally concealing or failing to disclose an event:

(a) that the person knows affects the initial or continued right to a benefit or payment under the Medicaid program of:

(i) the person; or

(ii) another person on whose behalf the person has applied for a benefit or payment or is receiving a benefit or payment; and

(b) to permit a person to receive a benefit or payment that is not authorized or that is greater than the payment or benefit that is authorized;

(3) knowingly or intentionally makes, causes to be made, induces, or seek to induce the making of a false statement or misrepresentation of material fact concerning:

(a) information required to be provided by a federal or state law, rule, regulation, or provider agreement pertaining to the Medicaid program;

(b) knowingly or intentionally charges, solicits, accepts, or receives, in addition to an amount paid under the Medicaid program, a gift, money, a donation, or other consideration as a condition to the

> provision of a service or continued service to a Medicaid recipient if the cost of the service provided to the Medicaid recipient is paid for, in whole or in part, under the Medicaid program.

487. Organon, Omnicare and PharMerica knowingly violated V.T.C.A. Hum. Res. Code § 36.002 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Texas Anti-Kickback Statute (V.T.CA Hum. Res. Code § 32.039), as described herein.

488. The State of Texas, by and through the Texas Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

489. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Texas's payment decision.

490. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Texas's loss, and a consequence of the scheme.

491. As a result of the Defendants' violations of V.T.C.A. Hum. Res. Code § 36.002, the State of Texas has been damaged in an amount far in excess of millions of dollars exclusive of interest.

492. There are no bars to recovery under V.T.C.A. Hum. Res. Code § 36.113(b), and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to V.T.C.A. Hum. Res. Code § 36.101 on behalf of themselves and the State of Texas.

493. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Texas in the operation of its Medicaid program.

WHEREFORE, Relators respectfully requests this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF TEXAS:

(1) Two times the amount of actual damages which the State of Texas has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty as described in V.T.C.A. Hum. Res. Code § 36.025(a)(3) for each false claim that Organon, Omnicare and PharMerica cause to be presented to the State of Texas;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to V.T.C.A. Hum. Res. Code § 36.110, and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

X. COUNT XXIV - VIRGINIA FRAUD AGAINST TAXPAYER ACT

494. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

495. This is a *qui tam* action brought by Relators and Commonwealth of Virginia to recover treble damages and civil penalties under the Virginia Fraud Against Taxpayer Act, Va. Code § 8.01-216.01 *et seq.*

496. Va. Code § 8.01-216.3 provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(3) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(4) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

497. Organon, Omnicare and PharMerica knowingly violated Va. Code § 8.01-216.3 from at least 1999 to 2005, including by their violations of f the Federal Anti-Kickback Statute and the Virginia Anti-Kickback Statute (Va. Code Ann. § 32.1-315), as described herein.

498. The Commonwealth of Virginia, by and through the Commonwealth of Virginia Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

499. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the Commonwealth of Virginia's payment decision.

500. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the Commonwealth of Virginia's loss, and a consequence of the scheme.

501. As a result of the Defendants' violations of Va. Code § 8.01-216.3 the Commonwealth of Virginia has been damaged.

502. There are no bars to recovery under Va. Code § 8.01-216.8, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Va. Code § 8.01-216.5 on behalf of themselves and the Commonwealth of Virginia.

503. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the Commonwealth of Virginia in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the COMMONWEALTH OF VIRGINIA:

(1) Three times the amount of actual damages which the State of Virginia has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Virginia;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Va. Code § 8.01-216.7 and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Y. COUNT XXV - WISCONSIN FALSE CLAIMS ACT

504. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 as if fully set forth herein.

505. This is a *qui tam* action brought by Relators and the State of Wisconsin to recover treble damages and civil penalties under the Wisconsin False Claims Act, Wis. Stat. Ann. § 20.931 *et seq.*

506. Wis. Stat. Ann. § 20.931(2) provides liability for any person who-

(1) knowingly presents, or causes to be presented, to an officer or employee of the State a false or fraudulent claim for payment or approval;

(2) knowingly makes, uses, or causes to be made or used, a false record or statement to get a false or fraudulent claim paid or approved by the State;

(5) conspires to defraud the State by getting a false or fraudulent claim allowed or paid;

(6) knowingly makes, uses, or causes to be made or used a false record or statement to conceal, avoid, or decrease an obligation to pay or transmit money or property to the governmental entity or its contractors.

507. Organon, Omnicare and PharMerica knowingly violated Wis. Stat. Ann. § 20.931(2) from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute, as described herein.

508. The State of Wisconsin, by and through the State of Wisconsin Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

509. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Wisconsin's payment decision.

510. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Wisconsin's loss, and a consequence of the scheme.

511. As a result of the Defendants' violations of Wis. Stat. Ann. § 20.931(2), the State of Wisconsin has been damaged.

512. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Wis. Stat. Ann. § 20.931 on behalf of themselves and the State of Wisconsin.

513. This Court is requested to accept pendent jurisdiction of this related state claim as it is predicated upon the exact same facts as the federal claim, and merely asserts separate damage to the State of Wisconsin in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare and PharMerica:

To the STATE OF WISCONSIN:

(1) Three times the amount of actual damages that the State of Wisconsin has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare and PharMerica;

(2) A civil penalty of not less than $5,500 and not more than $11,000 for each false claim that Organon, Omnicare and PharMerica caused to be presented to the State of Wisconsin;

(3) Prejudgment interest; and

(4) All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

(1) The maximum amount allowed pursuant to Wis. Stat. Ann. § 20.931(11) and/or any other applicable provision of law;

(2) Reimbursement for reasonable expenses that Relators incurred in connection with this action;

(3) An award of reasonable attorneys' fees and costs; and

(4) Such further relief as this Court deems equitable and just.

Z. COUNT XXVI – CONNECTICUT ACT IMPLEMENTING THE PROVISIONS OF THE BUDGET CONCERNING HUMAN SERVICES AND MAKING CHANGES TO VARIOUS SOCIAL SERVICES STATUTES (Conn. Pub. Act. No. 09-5)

536. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

537. This is a *qui tam* action brought by Relator and the State of Connecticut to recover treble damages and civil penalties under the Connecticut Act Implementing the Provisions of the Budget Concerning Human Services and Making Changes to Various Social Services Statutes, Conn. Pub. Act. No. 09-5.

538. Conn. Pub. Act No. 09-5, § 2 provides liability for any person who

(a) knowingly presents, or causes to be presented, to an officer or employee of the state a false or fraudulent claim for payment or

approval under medical assistance programs administered by the Department of Social Services;

(b) knowingly makes, uses or causes to be made or used, a false record or statement to secure the payment or approval by the state of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;

(c) conspires to defraud the state by securing the allowance or payment of a false or fraudulent claim under medical assistance programs administered by the Department of Social Services;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement to conceal, avoid or decrease an obligation to pay or transmit money or property to the state under medical assistance programs administered by the Department of Social Services.

539. Omnicare, Organon, and PharMerica knowingly violated Conn. Pub. Act No. 09-5, § 2 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute and the Connecticut laws prohibiting kickbacks (Conn. Gen Stat. §§ 53a-161c, 53a-161d), as described herein.

540. The State of Connecticut, by and through the medical assistance programs administered by the Connecticut Department of Social Services, paid the false and/or fraudulent claims.

541. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of Connecticut's payment decision.

542. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of Connecticut's loss, and a consequence of the scheme.

543. As a result of the Defendants' violations of Conn. Pub. Act No. 09-5, § 2, the State of Connecticut has been damaged.

544. There are no bars to recovery under Conn. Pub. Act No. 09-5, § 9, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Conn. Pub. Act No. 09-5, § 4(a) on behalf of themselves and the State of Connecticut.

545. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of Connecticut in the operation of the medical assistance programs administered by the Connecticut Department of Social Services.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Omnicare, Organon, and PharMerica:

To the STATE OF CONNECTICUT:

- Three times the amount of actual damages which the State of Connecticut has sustained as a result of the fraudulent and illegal practices of Omnicare, Organon, and PharMerica;
- A civil penalty of up to $10,000 for each false claim that Omnicare, Organon, and PharMerica presented or caused to be presented to the State of Connecticut;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

- The maximum amount allowed pursuant to Conn. Pub. Act No. 09-5, § 6(b) and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;

- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

AA. COUNT XXVII – NORTH CAROLINA FALSE CLAIMS ACT (N.C. Gen. Stat. § 1-605 *et seq.*)

546. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

547. This is a *qui tam* action brought by Relator and the State of North Carolina to recover treble damages and civil penalties under the North Carolina False Claims Act, N.C. Gen. Stat. § 1-605 *et seq.*

548. N.C. Gen. Stat. § 1-607 provides liability for any person who

(a) knowingly presents or causes to be presented a false or fraudulent claim for payment or approval;

(b) knowingly makes, uses, or causes to be made or used, a false record or statement material to a false or fraudulent claim;

(c) conspires to commit a violation of § 1-607;

(d) knowingly makes, uses, or causes to be made or used, a false record or statement material to an obligation to pay or transmit money or property to the State of North Carolina, or knowingly conceals or knowingly and improperly avoids or decreases an obligation to pay or transmit money or property to the State of North Carolina.

549. Organon, Omnicare, and PharMerica knowingly violated N.C. Gen. Stat. § 1-607 from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute, as described herein.

550. The State of North Carolina, by and through the North Carolina Medicaid program and other state health care programs, paid the false and/or fraudulent claims.

551. Given the structure of the health care systems, false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the State of North Carolina's payment decision.

552. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the state Medicaid programs was a foreseeable factor in the State of North Carolina's loss, and a consequence of the scheme.

553. As a result of the Defendants' violations of N.C. Gen. Stat. § 1-607, the State of North Carolina has been damaged.

554. There are no bars to recovery under N.C. Gen. Stat. § 1-611, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to N.C. Gen. Stat. § 1-608(b) on behalf of themselves and the State of North Carolina.

555. This Court is requested to accept pendent jurisdiction over this related state claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the State of North Carolina in the operation of its Medicaid program.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare, and PharMerica:

To the STATE OF NORTH CAROLINA:

- Three times the amount of actual damages which the State of North Carolina has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare, and PharMerica;

- A civil penalty of up to $11,000 for each false claim that Organon, Omnicare, and PharMerica presented or caused to be presented to the State of North Carolina;
- Prejudgment interest; and
- All costs incurred in bringing this action.

TO RELATORS BANIGAN AND TEMPLIN:

- The maximum amount allowed pursuant to N.C. Gen. Stat. § 1-610 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

BB. COUNT XXVIII –CITY OF CHICAGO FALSE CLAIMS ACT

556. Relators repeat and reallege each allegation contained in paragraphs 1 through 283 above as if fully set forth herein.

557. This is a *qui tam* action brought by Relators and the State of North Carolina to recover treble damages and civil penalties under the Chicago False Claims Act, Municipal Code of Chicago § 1-22-010 - §1-22-060.

558. Organon, Omnicare, and, PharMerica knowingly violated the Chicago False Claims Act from at least 1999 to 2005, including by their violations of the Federal Anti-Kickback Statute, as described herein.

559. The City of Chicago paid the false and/or fraudulent claims.

560. Given the structure of the health care systems, the false statements, representations, and records made by Organon, PharMerica, and Omnicare had the potential to influence the City of Chicago's payment decision.

561. The ultimate submission by long-term care pharmacy providers, retail pharmacy chains, mail-order pharmacies, and managed care pharmacies of false claims to the City of Chicago was a foreseeable factor in the City of Chicago's loss, and a consequence of the scheme.

562. As a result of the Defendants' violations of Municipal Code of Chicago § 1-22-020, the City of Chicago has been damaged.

563. There are no bars to recovery under Municipal Code of Chicago § 1-22-030, and, or in the alternative, Relators are original sources as defined therein. Relators are private persons with direct and independent knowledge of the allegations of this Complaint, who have brought this action pursuant to Municipal Code of Chicago § 1-22-030 on behalf of themselves and the City of Chicago.

564. This Court is requested to accept pendent jurisdiction over this related claim as it is predicated upon the same exact facts as the federal claim, and merely asserts separate damages to the City of Chicago.

WHEREFORE, Relators respectfully request this Court to award the following damages to the following parties and against Organon, Omnicare, and PharMerica:

To the CITY OF CHICAGO:

- Three times the amount of actual damages that the City of Chicago has sustained as a result of the fraudulent and illegal practices of Organon, Omnicare, and PharMerica;
- A civil penalty of up to $10,000 for each false claim that Organon, Omnicare, and PharMerica presented or caused to be presented to the City of Chicago;
- Prejudgment interest; and
- All costs incurred in bringing this action.

To RELATORS BANIGAN AND TEMPLIN:

- The maximum amount allowed pursuant to Municipal Code of Chicago § 1-22-030 and/or any other applicable provision of law;
- Reimbursement for reasonable expenses that Relators incurred in connection with this action;
- An award of reasonable attorneys' fees and costs; and
- Such further relief as this Court deems equitable and just.

CC. COUNT XXIX–COMMON FUND RELIEF

565. Relators repeat and reallege each allegation contained in paragraphs 1 through 564 above as if fully set forth herein.

566. While the states possessing *qui tam* statutes have a regulatory scheme for rewarding the Relators for coming forward, those which have none will potentially receive a windfall with little or no investigation or commitment of time or resources to the recovery. The Common Fund doctrine preserves the right of the litigant or counsel to an award from the Common Fund generated. The United States Supreme Court, and many others, have addressed this situation. *Boeing Company v. Van Gemert*, 444 U.S. 472 478 (1980):

> Since the decisions in *Trustees v. Greenough*, 105 U.S. 527, 26 L.Ed. 1157 (1882), and *Central Railroad & Banking Co. v. Pettuss*, 113 U.S. 116, 5 S.Ct. 387, 28 L.Ed. 915 (1885), this Court has recognized consistently that a litigant or a lawyer who recovers a common fund for the benefit of persons other than himself or his client is entitled to a reasonable attorney's fee from the fund as a whole. [citations omitted]. The common-fund doctrine reflects the traditional practice in courts of equity, *Trustees v. Greenough*, supra 105 U.S., at 532-537, and it stands as a well-recognized exception to the general principle that requires every litigant to bear his own attorney's fees [citations omitted]. The doctrine rests upon the perception that persons who obtain the benefit of the lawsuit without contributing to its cost are unjustly enriched at the successful litigant's expense [citation omitted]. Jurisdiction over the fund involved in the litigation allows a court to prevent this inequity by assessing attorney's fees against the entire fund, thus

> spreading fees proportionally among those benefitted by this suit. [citations omitted].

Accord, *In re Smithkline Beckman Corp. Securities Litig.*, 751 F. Supp. 525, 531 (E.D. Pa. 1990). There are a huge string of cases which recognize the Common Fund doctrine for situations like that in this case. See "The Common Fund Doctrine: Coming of Age in the Law of Insurance Subrogation," 31 Ind. L. Rev. 313, 337-38 (1998). Relators respectfully request this Court to award them a percentage share from the Common Fund generated by her actions.

XVI. DEMAND FOR JURY TRIAL

567. Pursuant to Federal Rule of Civil Procedure 38, Relators demand a trial by jury.

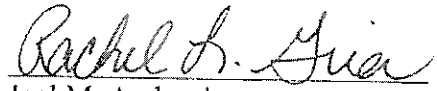
WHEREFORE, Relators respectfully request all relief described herein.

Dated March 18, 2010

UNITED STATES OF AMERICA, *ex rel.*
James Banigan and Richard Templin

Respectfully submitted,

BERG & ANDROPHY



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CERTIFICATE OF SERVICE

I hereby certify that on March 4, 2010, a true and correct copy of Relators' Motion for Leave to File Second Amended Complaint, together with a copy of the proposed filing attached to that motion as Exhibit A, was forwarded via the United States Mail, certified, return receipt requested, by facsimile, or by messenger to the United States Attorney's Office in the District of Massachusetts, and the Department of Justice in Washington, D.C., and the Attorneys General of the Qui Tam States and the District of Columbia. On March 18, 2010, true and correct copies of the foregoing document, which is identical to the proposed filing except as to title, date, and certificate of service, were forwarded via electronic mail to the United States Attorney's Office in the District of Massachusetts, the Department of Justice in Washington, D.C., and the Attorneys General of the Qui Tam States and the District of Columbia.

Rachel L. Grier